# AN OPEN CLINICAL STUDY ON "MERUGULLI THYLAM" (INTERNAL) IN THE TREATMENT OF VALI AZHAL KEELVAYU (RHEUMATOID ARTHRITIS)

The Dissertation Submitted by

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# DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "AN OPEN CLINICAL STUDY ON MERUGULLI THYLAM (INTERNAL) IN THE TREATMENT OF VALI AZHAL KEELVAYU (RHEUMATOID ARTHRITIS)

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Siddha system is one of the major system of medicine indigenous to our country. Siddha system can be termed as a scientific art which proves that health soul is the property of a healthy body.

Siddha system of medicine not only deals with external body but also with the inner man or the soul.

The word Siddha means "established truth" and comes from the word siddhi an object to be attained such as perfection in life or heavenly bliss.

The concepts of Siddha system are based on fundamental principles of five basic elements of the universe, three humours , three thathus and seven pillars (Physical constituents of the body), Envagai thervugal (An integral part of Siddha Medicine).

The physical function of the body is mediated by three forces called vali, azhal, iyam. In normal state they are called three forces or three thathu that sustain and nourish the body. When the three humours are deranged, they become Kutrams which produce disease.

Humoural basis of disease diagnosis is needed to select humour based treatment, which can result in better prognosis.

Thiruvalluvar says this way of approach in the following lines;

"Meginum kuraiyinum noi seiyum noolor

Valimudhala enniya moondru"

## - Thirukkural

When this equilibrium is disturbed, it leads to ailment, which hinders longevity.

The holistic approach adopted by the Siddha system of medicine is very aptly captured by the basic quote of Siddhars "FOOD ITSELF IS MEDICINE –MEDICINE ITSELF IS FOOD".

Sivavaakiyar says in Sattamuni gnanam;

'Andathil ullathae pindam'

Which means, what is in the Macrocosm (world/Universe) is in Microcosm (Man). Siddha claims that the human body is the replicate of universe. In Siddha system, Yugimuni classified diseases into 4448. Yugimuni mentioned 80 types of vatha diseases in the text Yugi Vaidhiya Chinthamani. In which Valiazhal keelvayu is one among them and the signs and symptoms of this disease is correlated with Rheumatoid arthritis in Modern science.

Rheumatoid arthritis (RA) is the most common persistent inflammatory arthritis, occurring throughout the world and in all ethnic groups. The clinical course is prolonged, with intermittent exacerbations and remissions. The typical clinical signs are pain, joint swelling and stiffness affecting the small joints of the hands, feet and wrist.

Incidence of RA is of 3 cases per 10,000 populations per annum. Onset is uncommon under the age of 15 and from then on the incidence rises with age until the age of  $80^{(1)}$ .

Prevalence of this disease affecting 0.75% population in India. Projected to the whole population, this would give a total of about 7 million patients. The prevalence of RA in India is quite similar to reported from the developed countries <sup>(2)</sup>.

Around 40% of RA patients are registered disabled within 3 years; around 80% are moderately to severely disabled within 20 years; and 25% will require a large joint replacement<sup>(1)</sup>.

Many formulations are available to treat Vali azhal keel vayu in Siddha system of medicine. I have chosen the drug "MERUGULLI THYLAM" (**Reference:** *Theraiyar Thylavarga Surukkam*, **P. No. :** 80-81**Author:** T.C.Subbramaniya Pandither) as internal medicine. This preparation reduced not only the joint pain but also the restricted movements and other symptoms of the disease Vali azhalkeel vayu.Because the ingredients of the drug are well known for its **Anti-inflammatory**, **Antioxidant**, **analgesic and Antibacterial activities** <sup>(3)</sup>.

# AIM

To Evaluate the Therapeutic efficacy of the siddha formulation "MERUGULLI THYLAM" (Internal) in the treatment of "VALI AZHAL KEELVAYU (Rheumatoid Arthritis)."

# **OBJECTIVES:**

# **PRIMARY OBJECTIVES:**

To Evaluate the Therapeutic efficacy of the siddha formulation "MERUGULLI THYLAM" (Internal) in the treatment of "VALI AZHAL KEELVAYU (Rheumatoid Arthritis)."

# **SECONDARY OBJECTIVES:**

- To conduct a clinical trial with a well defined Performa on identical patients with vali azhal keelvayu.
- To study vali azhal keelvayu, on the siddha basic principles like Mukkutram, Udalkattugal, Envagai thervu, pori, pulan, Neerkkuri and Neikkuri pattern etc in vali azhal keelvayu patients.
- To correlate the aetiology, clinical features, signs and symptoms of vali azhal keelvayu in Siddha system to Rheumatoid Arthritis in Modern science.
- To screen the elements present in the trial drug.
- To screen the biochemical constituents of the drug.
- To study the influence of other co factors such as Age, Sex, Socio-economic status, Dietary Habits, Family history etc.,
- To find out whether there are any side effects/ adverse effects produced by the trial drug MERUGULLI THYLAM (Internal) during treatment.

# REVIEW OF LITERATURE SIDDHA ASPECT

Siddha system was propounded by the siddhars and which is a vast and unique system which defines health as a perfect state of physical, psychosocial, social and spiritual well being of an individual.

The system not only deals with medicinal but with spirituality, righteous way of living, Rejuvenation and its main aim is attainment of perfection.

## **VATHA NOI - DEFINITION**

Vatha noi is a clinical condition characterised by pain, swelling, pricking sensations and loss of function due to vitiated vatham which is the principle humour of the body.

"பொற்றா மரையான் புனைமெய் யரண்காக்கும் பொற்றா மரையான் புகல்வதென் பொற்றாம் வளவினிலே யாக்குரம்பை மன்னனென மன்ன வளவினிலே யாக்கும் வளி".

–தேரன் யமக வெண்பா

The above verse says that, vatham is being held as the king who rules the (fort) body and enables the wellbeing of the citizen (the uyir) in the fort. Hence, Theraiyar refers Vatham as prime force in normal state.

For wellbeing of a individual three vital humours should be maintained in a equilibrium state. If there is a imbalance in any one of them it will alter the other two resulting in a diseased condition.

## CHARACTERISTICS OF VATHA DISEASES

"பாங்கான வாதந்தான் மீறுமாகிற் பருவயிறு சுவாசமுடன் குத்துக்கோழை நீங்காத பிழப்புளைவு வாயு தொந்தம் நீர்வெடித்துப் பாய்தல் மந்தம் விடமிப்பாதல் தூங்குசன்னி வாதசுர மதனிற் தோடம் தொகுத்த கிரா ணிக்கழிச்ச லுதர தோடம் வாங்குபல வலிகுளிர்ச்சி குன்மவாத மலசலங்கட் டிடல்வாத வந்திப்பாமே."

-அங்காதிபாதம்

According to Angaathipatham the deranged Vali produces constipation, scanty micturation, increased lacrimation, with darkening of eyes, fissures in tongue, flatulence, abdominal distension, cough with expectoration, dysarthria, indigestion and diarrhoea.

"மேவியவாதஞ் செய்யுங் குணந்தணை வியம்பக் கேளாய் தாவியே வயிறு தந்தஞ் சந்துகள் பொருத்து நோவாஞ் சீவிய தாதுநாசஞ் செறுத்துடன் சிறுநீா் வீழுங் காவியங் கண்ணி னாளே மலமது கருகிவீழும்."

-அகத்தியர் வாத காவியம்-1000

"வாதத்தின் குணமேதென்னில் வயிறது பொருமிக்கொள்ளுந் தாதுகளுலர்ந்த கைகால் சந்துகள் கடுப்புத் தோன்றுந் தீதுற்றச் சிறுநீர்தானுஞ் சிறுத்துடன் கடுத்து வீழும் போதுற்ற வாதமென்று புகன்றனர் முனிவர் தாமே." - **கண்ணுசாமியம்** 

According to Agathiyar vatha kaaviyum and kannusamiyam the deranged Vatham produces abdominal discomfort, pain in joints , oliguria, dysuria, constipation and flatulence.

## VALI AZHALKEEL VAYU

# **Definition (Iyal)**

Vali azhal keelvayu is a type of Arthritis characterised by pain, swelling, stiffness of the joints and restriction of movements due to deranged vatham and pitham.

# VALI AZHAL KEEL VAYU mentioned in Sababathi kaiyedu which indicates Uthiravatha suronitham.

# **DESCRIPTION OF NOMENCLATURE:**

According to T.V.Sambasivampillai Agarathy volume I				
Uthiravatha Suronitham	-	Uthiravatham + Suronitham		
Uthiravatham -		Arthritis of rheumatic origin marked by severe		
		pain and the formation of inflammatory nodules in the		
		region of joints especially in the limbs of the body.		
Suronitham	-	Blood and menstrual blood.		

## நோய் வரும் வழி -AETIOLOGY

According to Yugi Vaithya Sinthamani,

"என்னவே வாதந்தா னெண்ப தாகும் மிகுத்திலே மனிதர்களுக் கெய்து மாறு பின்னவே பொந்தனையே சோரஞ் செய்து பெரியோர்கள் பிராமணரைத் தூஷ் ணித்தும் வன்னவே வச்சொத்திற் சோரஞ் செய்து மாதாபிதா குருவை மறந்து பேர்க்கும் கன்னவே வேதத்தை நிந்தைசெய்த பேர்க்குங் காயத்திற் கலந்திடுமே வாதந் தானே. "தானென்ற கசப்போடு துவர்ப்பு ரைப்பு சாதகமாய் மிஞ்சுகினுஞ் சமைத்த வன்னம் ஆனென்ற வாறினது பொசித்த லாலும் ஆகாத் தேறலது குடித்த லாலும் பானென்ற பகலுறக்க மிராவி ழிப்பு பட்டினியே மிகவுறுதல் பார மெய்தல் தேனென்ற மொழியாற் மேற் சிந்தை யாகில் சீக்கிரமாய் வாதமது செனிக்குந் தானே." "ஆணான வரன்னௌயே மதியா மாந்தர் அகதிபர தேசியாகட் கன்ன மீயாா் கோனான குரமொழியை மறந்த பேர்கள் கொலைகளவு பொய்காமங் குறித்த போக்கு ஊனான சடந்தன்னில் வாதம் வந்து உற்பவிக்கும் வேதத்தி லுண்மை தானே."

# -யூகி வைத்திய சிந்தாமணி

According to the text, those who are squandering money, insulting the elders, abandoning or forgetting the parents, blaspheming the Holy books, not respecting the divine gifts, having wickedness in their mind and those with day slumber and staying back at night will get Vatha diseases. Increased intake of bitter taste, astringent, pungent, increased intake of water, excessive starvation, increased sexual desire will produce diseases of vatham.

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## IN THE TEXT ANGAATHIPATHAM..,

"கானடையாலச் சத்தாற் கடும்பசி யாற்கோ பத்தால் ஊனமி லிரவில் வார்த்தை யுரம்பெற விரைக்க லாலூண் ஆனபின் முனிவால் மாரு தடுத்தடுத் துரைக்குஞ் சொல்லால் ஈனமி லிகழ்ச்சி யான விகல்வாத கோபங் காணும்."

According to Angaathipatham, increased starvation and increased anger will produce diseases of vatham.

# OTHER IMPORTANT FACTORS THAT INFLUENCE THE VATHA TYPE OF DISEASE:

கால இயல்பு - ENVIRONMENTAL FACTORS;

## AS PER SIDDHA MARUTHUVAANGA CHURUKKAM

"பதுமத்தைப் பூக்க வைக்கும் பானுமிகக் காயும் முதுவேனி லிற்பு விற்நீா முற்றும் -கதுமென வற்றும் கபமி.கும் வாயுமிகும் வாழ்மாந்தக் குற்ற நலிக் கேதிதென் றோது"

## -சித்த மருத்துவாங்க சுருக்கம்

In Muthuvenil kaalam (Late summer), the increased solar radiation increases the evaporation of water content from the body in turn produces increase in the Kapham and Vatham thus resulting in the production of vatha disease.

"ஆடியாதியாய் ஐப்பசி ஈறாய் அனிலமதற் கோரரசியல் காலம்."

- நோய் நாடல் நோய் முதல் நாடல் திரட்டு II

Vatham elevates in the body from the month of Aadi to Iyppasi (August to November) i.e. from the middle of Muthuvenil kaalam, Karkaalam to half of Koothir kalam.

## HABITS THAT MAY CAUSE VATHA DISEASES

1. In Theraiyar vagadam it is explained as..,

"வெய்யிலில் நடக்கையாலும் மிகத்தண்ணீர் குடிக்கையாலும் செய்யிழை மகளினரைச் சேர்ந்தனுப விக்கையாலும் பையனே உண்மையாலும் பாகற்காய் தின்கையாலும் தையலே வாத ரோகம் சனிக்கு மென்றறிந்து கொள்ளே."

- தேரையர் வாகடம்

Excessive walking in hot sun, excessive intake of water, bitter guard and increased sexual indulgence, may play a role in disturbing the normal functions of Vatham

## TASTES THAT MAY INCREASE THE VATHA KUTARM

"புளிதுவர் விஞ்சும் கறியால் பூரிக்கும் வாதம"

- நோய் நாடல் நோய் முதல் நாடல் திரட்டு

"வளிதருகாய் கிழங்கு வரைவிலா தமிலல் கோழை புளி தயிர் போன் மிருக்கு முறையிலா வுண்டி கோடல் குளிர் தரு வளியிற் றேகங் குனிப்புற வுலவல் பெண்டிர் குளி தரு முயக்கம் பெற்றோர் கடி செயல் கருவியாமால்" -சபாபதி கையேடு

According to Sababathi Kaiyedu, increased intake of tubers, increased exposure to wind, living in higher altitudes, increased exposure to chill, increased sexual desire will aggravate Vali dieases.

"தொழில் பெறு கைப்புக் கார்த்தல் துவர்த்தல் விங்கினுஞ் சோறும் பழையதாம் வரகு மற்றைப் பைந்தினையருந்தினாலும் எழில் பெறப் இரவினிலுறங்காததாலும் மழைநிகா குழலினாலே வாதங்கோ பிக்குங்காணே" - பரராச சேகரம்

Increased intake of bitter, astringent, acrid taste food, altered sleep pattern contribute to vatha diseases.

## CLINICAL FEATURES OF VALI AZHALKEEL VAYU

## ACCORDING TO SIDDHA MARUTHUVAM POTHU

"வாதபித்தக் கீல் வாய்வின் வருங்குறி சாற்றக் கேளாய் ஏதமார் மந்த மேப்பம் இரைச்சலும் வயிற்றிற்காணும் ஓதருங் குத்தல் வீக்கம் ஓய்தலில் எரிச்சலுண்டாம் காதறுமுறக்க மின்மை காய்சசலும் காணுங்கண்டாய்"

It is characterized by belching, prickling pain, swelling, irritation, fever and lack of sleep.

## ACCORDING TO YUGI VAITHIYA SINTHAMANI

"வைகிதமாய்க் கணைக்காலு முழங்கால் தானும் மற்கடஞ் சந்து புறவடியும் வீங்கிச் செய்கித மாற் சிறுவிரல்கள் மிகவும் நொந்து சிந்தை தடுமாறியே சலிப்புணடாகும் பைகிதமாம் பயித்தியத் தில்லாத மிஞ்சிப் பாரமாய் உற்பவித்து அழலுண்டாகும் உய்கிதமாம் அசனமது தானும் வேண்டா உதிர வாத சுரோணிதத்தி னுணர்ச்சியாமே." - **யூகி வைத்திய சிந்தாமணி** 

It is characterised by pain and swelling in both ankle joints, knee joints and all smaller joints of the hands, feeling of tiredness, fever, loss of appetite and mental depression.

Also the term 'Markadam' (شأنهدن) indicates the hand of monkey (**T.V.Sampasivam Pillai dictionary Pg no: 753**) anatomically, which can be correlated clinically with Swan neck deformity and wasting of tenar muscle in Rheumatoid Arthritis. '**Pararasa sekaram'** describes Suronitham as follows:

"வீழ்பெறு சுரோணிதந்தான் மிகவுடன் மெலிவுமாகித் தாழ்வில் சந்துகளே வீங்கித் தகை பெற நடைகொடாமல் வாழ்வுறு கையுங்காலும் வசமின்றி யழன்று நோவாம் பாழ்பெறு மணங்கினாளே பயனுறப் பகர்ந்திட்டோமே"

It is characterized by debility in Ratha thathu (anaemia), swelling of peripheral joints, restricted movements and pain in limbs.

# ACCORDING TO 'PARA RASA SEKARAM':

"பக்கமும் மார்பும் கூடப்பற்றியே இழுத்தும் கொண்டு நெக்கியே மார்பிளைத்து தோதாய் நரம்பிழுத்து ஒக்கவே சயித்தியங்கள் உயர்ந்துடன் மேலும் காலம் மிக்குமே உதிரவாதம் என்றிது விளம்பலாமே."

பரராச சேகரம்

It is characterised by pain and tenderness of the axilla, breathlessness, pain in the upper limbs and the lower limbs.

# SIDDHA PATHOLOGY

Siddha system of medicine is based on Thirithodam theory. They are Vatham, Pitham and Kabam the manifestation of all diseases are result of derangement of these Uyir thathus (Thirithodam).

These three humours are primary and essential factors of human body. These factors exist in 1:1/2:1/4 ratio respectively in the normal body any alteration in the above ratio can cause disease in the body.

In Vali azhal keelvayu

1. Vatham - increased

"வாதமலாது மேனிகெடாது" **– தேரையர்** 

2. The increased vatha kutram causes derangement of other two kuttrams (ie. Pitham and Kabam) as a result of this clinical features of disease is exhibited.

## DIAGNOSIS - நோய்கணிப்பு

"நோய்நாடி நோய்முத னாடி யதுதணிக்கும் வாய்நாடி வாய்ப்பச் செயல்"

## திருக்குறள்

This Thirukural quote explains the importance of diagnosis, as it is to be made in order of the aetiology, root of cause of the disease thereby treating the disease with appropriate medicine.

## Piniyari muraigal (Method of Diagnosis)

It is based upon the three main principles:

- Poriyal Arithal (Inspection)
- Pulanal Arithal (Palpation)
- Vinaathal (Interrogation)

# DIAGNOSTIC METHODOLOGY IN SIDDHA SYSTEM OF MEDICINE ENVAGAI THERVUGAL (EIGHT DIAGNOSTIC TOOLS)

These tools not only help in the diagnosis but also helps to observe the prognosis of the diseases and for reassuring the patient and to be informed about the nature of diseases, they are

- 1. Naadi (Pulse)
- 2. Sparisam (Sensation to Touch)
- 3. Naa (Tongue)
- 4. Niram (Colour)
- 5. Mozhi (Voice)
- 6. Vizhi (Eyes)
- 7. Malam (Faeces)
- 8. Moothiram (Urine)

# I. Naadi (Pulse):

Naadi is the first and foremost diagnostic parameter of the Siddars. It is the seat anchor of energy. The pulse wave as felt on the radial artery, one inch from the wrist by means of palpation with the tip of index, middle and ring finger corresponds to VATHAM, PITHAM,KABAHAM. They normally exit in the ratio 1:1/2:1/4 respectively.

# In VALI AZHAL KEELVAYU the following types of Naadi can be commonly seen.

They are

- Vadhapitham
- Pithavadham
- Vadhakabam

''திருத்தமாம் வாதந்தோடே தீங் கொடு பித்தஞ் சேரில் பொருத்துகள் தோறும் நொந்து''

-குணவாகடம் (நோயின் சாரம்)

According to Gunavagadam, vathapiha naadi seen in VALI AZHAL KEELVAYU.

## **II. Sparisam (Touch):**

Inspection and Palpation of the skin, it reveals that the warmth or chillness, dry or weeping skin, rough or smooth, tenderness, swelling, wrinkle, soft or hard ,any ulcers or fissures etc. In Valiazhal keelvayu mild warmth is felt over the affected joints with swelling, tenderness and sometimes subcutaneous nodules and the degree of warmth may vary from to other depending on the severity of disease.

## **III.** Naa (Tongue Examination)

The colour, character and condition of tongue are noted.

In Vali azhalkeelvayu tongue commonly does not show any abnormality. In cases with anaemia it may appear pallor, glossy and coated.

# IV. Niram (Colour)

Signs of different complexions in Vatham, Pitham, Kabham and Thontha thegis, cyanosis, pallor, yellowish discolouration may be noted.

In Vali azhalkeelvayu no abnormalities are seen normally. Sometimes pallor of skin may be noted in case of anaemia.

# V. Mozhi:

It constitutes high ,low-pitched voice, nasal speech, horsiness of voice, slurring and incoherent speech etc.

In Vali azhalkeelvayu no abnormalities are seen normally.

## VI. Vizhi:

Both motor and sensory disturbances of eyes noticed. Redness of eyes, paleness, swelling, excessive lacrimation, corneal ulcers may be noted .

In Vali azhalkeelvayu no abnormalities are seen normally. In anaemic patients pale conjunctiva may be noted.

## VII. Malam:

Vatha type: Black coloured stool with constipation.

Pitha type: Loose stools with yellowish red colour.

Kabha type: White coloured stools with mucus.

Thontha type: Stools possess of the features of two thonthams.

In Vali azhalkeelvayu constipation was reported in most of the cases.

## VIII. Moothiram:

Neerkuri and Neikuri are special diagnostic methods regarding moothiram.

# NEERKURI: (PHYSICAL EXAMINATION OF URINE)

The urine is collected and examined for the following.

Niram	-	Colour
Edai	-	Specific Gravity
Manam	-	Smell
Nurai	-	Frothy Nature
Enjal	-	Deposits/ quantity of urine voided

In Vali azhalkeelvayu straw or hay coloured urine is noticed in Neerkuri.

# **NEIKURI: (OIL ON URINE SIGN)**

When the oil drops lengthens like a snake it indicates "Vatha neer".

When the oil drops spreads like a ring it indicates "Pithaneer"

When the oil drops remains that of pearl it indicates "Kabaneer".

In Vali azhalkeelvayu the pattern of Neikuri is mostly "Aravena neendathu -

Vatham". In some cases the oil drop remain as that of a pearl or ring indicating Kaba neer. Pitha neer accordingly.

## **MUKKUTRAM**:

## VATHAM: [BIO ENERGY MOVEMENTS]

When some of the factors like food, occupation, seasonal variations etc., disturb Vatham, it looses its control, which may be exaggerated or diminished. So the other two Uyir Thathus are also disturbed which leads to the genesis of "Vatha" diseases. Uyir thathu can be termed as "Vatha thodam".

# The sites of vatham :

Umbilicus, Abdomen, Rectum, Faecal matters, Anus, Bones, Hip joints, Joints, Navel, Plexus, Hair follicle and Muscles.

"நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய் நாபிக்குக் கீழென்று நவில லாகும்"

் யூகி முனி

"அறிந்திடும் வாத மடங்கு மலத்தினில்"

திருமூலர்

According to Yugi muni and Sage Thirumoolar the location of Vatham are the anus and the sub naval region.

# Natural properties of Vatham:

- Giving briskness
- Functions of mind
- Expiration and inspiration
- Regulation of the "Fourteen Physical Reflexes" (Vegam).
- Protection and strengthening of the five sensory organs (Iymporigal).

## Symptoms of Vatha thodam:

- ✤ Body ache
- Pricking pain
- Nerve weakness
- ✤ Tearing pain
- ✤ Joints pain
- ✤ Traumatic pain
- Mental distress
- ✤ Weakness of organs
- Paralysis of limbs
- Severe pain in calf and thigh muscles
- Bony pricking pain
- Unable to flexion and extension of the limbs
- Excessive salivation
- ✤ All tastes to be like astringent
- Polydypsia
- ✤ Anuria and constipation

## **DESCRIPTION OF VATHAM: BIO ENERGY MOVEMENTS**

The Siddha classical texts divide the general principles of Vatham into ten subsidiary forms that differ from one another by their localization in the body (Anatomical) and by their particular functions (Physiological). They are

## PRAANAN: Life force/Life air

It is otherwise called as "*Uyirkkaal*". It refers to be "*Heart centre*". It maintains the action of the heart, the functioning of the mental faculties of perception and concentrations and also cares for the arteries, veins and nerves. It also regulates the respiration and digestion.

## ABAANAN: [Downward air]

It is otherwise termed as "*Keezhnokkumkaal*", "Moolaadharam centre". It corresponds to the pelvic area and controls the excretion. It occupies the sites in the bladder and genitals and focussed in the lower part of the gut . It has a tendency to travel downwards. It moves in the whole Genitourinary tract and regulates the defecation. menstruation, parturition and ejaculation.

## VIYAANAN: [Centrifugal air]

It also known as "*Paravukaal*", "*Forehead centre*". It corresponds to the naso cilary area i.e at the root of the nose and base of the skull and controls the will. It helps in the circulation of energy throughout the entire nervous system and the movements of the various parts of the body.

### **UDHAANAN:** [Upward air]

It is otherwise named as "*Melnokkukaal*", "*Throat centre*". This corresponds to the pharyngeal area in the throat region and controls speech and breathing and also physiological reflex actions like vomiting, hiccup, cough etc. It has the tendency to travel upwards.

#### SAMAANAN: [Homeostatic air]

It balances the other vayus. It is also called *"Nadukkaal"*, *"Navel centre"*. It corresponds to the navel region and controls digestion. It selects the useful substances from the swallowed food and supplies them to the whole body.

## NAAGAN: [Intellectual air]

It is responsible for the intelligence of an individual, wrinkling, singing and pilo erection.

## **KIRUGARAN:** [Secretary air]

It is responsible for salivation and nasal secretion. It helps to indigestion and meditation. It produces cough and sneeze.

## **DHEVATHATHAN:** [Tiresome air]

It is responsible for laziness, lassitude, quarrelling, arguing, and also for much anger. It helps to movements of the eyeball in various directions and is present in genital and anal region.

## **DHANANJEYAN:** [Intracranial air]

It is present in nose and responsible for swelling of the body and tinnitus. It leaves the body by blowing up the cranium only on the third day after death.

In Vali azhalkeelvayu,

•	Abanan	- affected (produces constipation).
•	Viyanan	- affected (produces restricted joint movements).
•	Samanan	- affected (due to derangement of other vayus).

# 2. PITHAM: BIO ENERGY FIRE

## The sites of Azhal:

According to **Vaithiya Sathagam**, the pingalai, Urinary bladder, Stomach and heart are the places where Azhal is sustained. In addition to the above places, the umbilicus, epigastric region, stomach, sweat, saliva, blood, Essence of food, eyes and skin where Azhal sustains.

According to Yugi muni says that the Azhal resides in urine and the places below the neck region.

### The character of Azhal:

It is responsible for the digestion, hunger, thirst, maintenance of the body temperature, vision, taste etc. Its other functions include thought, knowledge, strength and softness.

## The types of Azhal

- Anala pitham The fire of digestion.
- Ranjaga pitham Haematinic fire.

- Saathaga pitham The fire of achievement.
- Prasaka pitham The fire of brightness.
- Alosaga pitham The fire of vision.

In case of Vali azhalkeelvayu,

Saathagam – affected (Difficulty in walking, climbing upstairs, squatting etc).

# **3.KABAM [Iyyam] –BIO ENERGY WATER**

# Sites of Iyyam

Head, tongue, eyes, nose, throat, thorax, bone, bone marrow, Joints, blood, fat, sperm and colon .

## The natural quality of Iyyam:

Stability, greasiness, formation of joints, thirst, the ability to withstand hunger, sorrow and distress are the qualities.

# Five types of Iyyam:

• Azhal Iyyam (Avalambagam)	- Nodal/Pivotal Iyyam- It controls all other 4 Iyyams.				
• Neerpi Iyyam (Kilethagam)	- Digestive/Aqueous Iyyam-It gives moisture and				
	softness to ingested food.				
• Suvaikaan Iyyam(Pothagam)	- Taste/gustatory Iyyam-It is responsible for the sense				
	of taste.				
• Niraivu Iyyam (Tharpagam)	- Coolant Iyyam-It gives coolness to the eyes.				
• Ondri Iyyam (Santhigam)	- Articular Iyyam-Its gives lubrication to the bones				
	particularly in the joints.				

In Vali azhalkeelvayu Santhigam is affected.

# UDAL KATTUGAL: SEVEN PHYSICAL CONSTITUENTS OF THE BODY:

In Vali azhalkeelvayu, the udal kattugal affected are

Saaram [Essence/chyme]	-	Weakness
Senner [Blood]	-	Tiredness, Anemia
Kozhuppu [Fat]	-	Pain in the affected joint
Enbu [Bone]	-	Weakness of bones
Moolai [Marrow]	-	Osteoporotic changes, Swelling in joints

# IV. GNANENTHIRIYAM [ORGANS OF PERCEPTION]

Gnanenthiriyam are Mei, Vaai, Kan, Mooku and Sevi.

In Vali azhalkeelvayu 'Mei' is affected. This is due to pain, swelling, morning stiffness and deformities.

# **IV.KANMENTHIRIYAM [MOTOR ORGANS]**

Kanmenthirium are Kai, Kaal, vaai, Eruvai, Karuvai.

In Vali azhalkeelvayu Kai and Kaal are affected. This is due to pain, swelling, morning stiffness and deformities.

# YUGI VAIDHYA CHINTHAMANI CLASSIFIED VATHA SURONITHAM INTO 7 TYPES.

- Vadha Suronitham
- Sithuvatha Suronitham
- Vaithiya Vatha Suronitham
- Paithiya Vatha Suronitham
- Slethumavatha Suronitham
- Utharavatha Suronitham
- Uthiravatha Suronitham

# **DIFFERENTIAL DIAGNOSIS**

Vali azhalkeelvayu is differentiated from other types of Vatha Suronitham as follows:

# வாதசுரோணிதம்

"அறிந்திட்ட அங்கமெல்லா மெலிவ தாகி

அசைவான தவ்விடங்கள் வீக்க மாகி

நறிந்திட்ட நடைகொடா தானி ருத்தல்

வலியாகி மொழிமொழிய வீக்க மாகச்

சொறிந்திட்ட தேகமெங்கு மசைவு காணல்

சோற்றின்மே னினையின்றித் தூக்க மாதல்

வுறிந்திட்ட வாயதனி னீர்தா நூறல்

வாதசுரோ ணிதந்தானும் வகுத்த வாறே."

-யூகி வைத்திய சிந்தாமணி

# VATHA SURONITHAM

- Emaciation
- Swelling of joints
- Restricted movements
- Joint pain
- Discomfort
- Excessive salivation
- Loss of appetite

## சித்துவாதசுரோணிதம்

"வாறான சரீரமெல்லா நுழைந்து ஊதல் மாசற்ற தோல்தானுந் திரைந்து போகும் நாறான நாறுபோல் நரம்பு சுக்கும் நாக்குத்தான் வழவழத்துக் கோழை யாகும் தூறான நெருப்புத்தான் பட்டார் போல நொந்துமே சடமெல்லாங் கொப்ப ளிக்கும் வீறான வரிந்துபின்னை வெதும் பீங்கும் மிக்கசித்து வாதசுரோ ணிதமா மாமே."

-யூகி வைத்திய சிந்தாமணி

# SITHUVATHA SURONITHAM

- Anasarca
- Wrinkles
- Neural pain
- Glossy tongue
- Sialorrhoea
- Bullous eruption as in burn
- Exfoliation, swelling and Warm

### பயித்தியவாதசுரோணிதம்

"உணர்ச்சியாய்ச் சுரோணிதந்தான் மிகவெ தும்பி ஊக்கமாய்த் தேகமெங்கு மிகவே நொந்து முணர்ச்சியாய் முழங்கால்கள் முழங்கை யொக்க முனையான சிறுவிரல்கள் கன்னம் நெற்றி தணர்ச்சியாய்ச் சந்துசரு வாங்க மெங்கும் தாட்டிக மாய்க்குடைந்து சுரமு முண்டாம்

பணர்ச்சியாய்ப் பாண்டதுபோன் மேனி யாகும்

பயித்தியவா தசுரோணிதத்தின் பண்பு தானே."

-யூகி வைத்திய சிந்தாமணி

# PAITHIYA VATHA SURONITHAM

- Hyperaemia
- Tenderness in knee, elbow and smaller joints
- Poly arthralgia
- Pyrexia
- Anaemia

## சேத்துமவாதசுரோணிதம்

"பண்பாக வுடல்குளிர்ந்து ஏறு வீங்கிப் பதைப்பான விடந்தொட்டாற் பார நோவாம் திண்பான சிரசுநெற்றி நோக்கா டுண்டாம் சிலேட்டுமமாய்க் கோழையொடு சுவாச மாகும் மண்பாக மயக்கமொடு கனவு முண்டாம் வாய்வரண்டு ருசியில்லா வருத்த மாகும் நண்பாக நாடியுமே படப ட்ககும் நற்சேட்ப சுரோணிதமாம் நாடுங் காலே"

-யூகி வைத்திய சிந்தாமணி

## **SLETHUMAVATHA SURONITHAM**

- Chillness with abdominal distension
- Severe pain and Head ache
- Syncope and Hallucination
- Dryness of mouth and Anorexia
- Tachycardia

## உதரவாதசுரோணிதம்

"நாடுமே சுரம்வந்து நடுக்க லுண்டாம் நாவரண்டு தலைநொந்து உடம் பழுத்தி வாடுமே தேகமெல்லா மனிச்சம் பூப்போல் மகாவருத்த முண்டாகி மயக்க மாகும் சாடுமே யடிக்கடிதான் பேதி தானும்

தவிக்குமே தண்ணீர்தா னாட்ட மாகித்

தேடுமே சோற்றின்மேல் நினைவு தானும்

செய்வுதர வாதசுரோ ணிதந்தா னென்னே."

-யூகி வைத்திய சிந்தாமணி

# UTHARAVATHA SURONITHAM

- Fever with rigor
- Dryness of mouth
- Pain in all over the joints
- Headache
- Diarrhoea
- Excessive thirst
- Hunger

## வைகிதவாதம்

"ஆமென்ற வீங்கினதோர் விடத்தில் ரத்தம்

அழுத்தமாய்த் திரண்டுமே எங்கும் பாய்ந்து

ஒமென்று ஒட்டியே திரண்டி ருக்கும்

உறுதியாய்த் தொட்டுடனே மெத்தென் றாகும்

தேமென்ற தேகமெங் கணுமு சுக்கும்

சீறியதோ ரிருமலொடு காச்சலுண் டாகும்

பாமென்ற படந்தனிலே திமிருண் டாகும்

பாரமாய் வைகிதமாம் வாதந் தானே."

-யூகி வைத்திய சிந்தாமணி

# VAIKITHA VATHA SURONITHAM

- Swelling with hyperaemia
- Soft on touch
- Cough with pyrexia
- Irritability

## MANAGEMENT IN SIDDHA

According to siddha system, the main aim of the treatment is to cure physical illness and mental illness Treatment is not only for complete healing but also for the rejuvenation.

> "மிகினும் குறையினும் நோய்செய்யும் நூலோர் வளி முதலா வெண்ணிய மூன்று"

> > –திருக்குறள்

Siddha system line of treatment consists of the following

1. Neekam (Treatment)

2. Niraivu (Restoration of wellbeing)

3. Kappu (Prevention)

## NEEKAM

a) To bring the Three Thodams to equilibrium state.

b) To treat the patient by Internal medicine.

c) To stabilize 7 Udal thadhukal and 3 Uyir thadhukal.

"விரேசனத்தால் வாதந் தாழும்"

## -சித்த மருத்துவாங்க சுருக்கம்

The trial drug MERUGULLI THYLAM (internally) was given on the first day of the treatment.

## NIRAIVU

By promoting the awareness about the dietary, seasonal, emotional influence on the disease assurance from disease recovery was given .Life-style modification was also advised to them.

"செங்கழுநீர் கோடைத் தேனமிளகு நல்லெண்ணெய் தங்கு பெருங்காயத் தழுதாழை – எங்கெங்கும் கட்டு சிறு முத்து நெய் கோதில் உளுந்திவைகள் வாட்டு மனிலத்தை மதி"

பதார்த்த குண சிந்தாமணி

Honey collected during summer, pepper, gingely oil, asafoetida, castor oil, oil and black gram are very useful in Vatha disease.

# KAAPU:

Knowing the cause there by removing it and thus preventing the disease is the main aim of Siddha system of medicine.

Siddha system emphasizes the purification of thought and activities as mentioned in the siddha text "Theraiyar Pinianuga Vithi" which emphasizes virtuousness to be followed even in the daily life activities.

# **DIETARY ADVICE**

In Siddha system of medicine the importance of dietary habits have been emphasised for the management of diseases and its prevention in a effective manner.

> கடுகு நற்றிலத் தெண்ணெய் கூழ்பாண்டங்கள் கடலை வருவதாகிய தெங்குமா வருக்கை நற்காயம் மடிவிலாத வெள்ளுள்ளிகொள் புகையிலை மதுபெண் இடறு பாகலோ டகத்தி நீக்கிடலிச்சா பத்தியம்"

> > -சித்த மருத்துவாங்க சுருக்கம்

"புளிதுவர் விஞ்சும் கறியால் பூரிக்கும் வாதம"

நோய் நாடல் நோய் முதல் நாடல் திரட்டு

During the course of treatment, the patients were advised to follow certain diet regimen (pathiyam) which is mentioned for vatha diseases.

\_

1. Kadugu	-	Brassica nigra. Linn. (Mustard seed)
2. Ell Nei	-	Gingelly oil
3. Poosanikkai	-	Bennicasa hispida. Thunb.
4. Kadalai	-	Arachis hypogeal. Linn.
5. Thengai	-	Coccus nucifera.Linn.
6. Mangai	-	Mangifera indica. <i>Linn</i> .
7. Pala	-	Artocarpus heterophyllus.Lam.
8. Kollu	-	Macrotyloma uniflorum.Lam.(Horse gram)
9. Pugaiyilai	-	Nicotiana tobaccum.Linn.
10. Pagal	-	Momordica charantia.Linn.
11. Agathi	-	Sesbania grandiflora.Linn.
12. Sour taste		

13. Astringent taste

# **MODERN ASPECT**

# INTRODUCTION

The bones of the skeleton are joined by a variety of structural arrangements collectively known as "Joints". Joints allow differential growth to the remission of forces and movements.

Normal structure of joints:

The joints are two types,

- 1. Diarthrodial or synovial joints with a joint cavity.
- 2. Synarthrodial or non synovial joints without a joint cavity.

Most of the diseases of joints affect diarthrodial or synovial joints. In Diarthrodial joints, the ends of the two bones are held together by joint capsule with ligaments and tendons inserted at the outer surface of the capsule. The articular surfaces of bones are covered by hyaline cartilage which is thicker in weight-bearing areas than in non weight-bearing areas. The joint space is lined by synovial membrane or synovium which forms synovial fluid that lubricates the joint during movements. The synovium may be smooth or thrown into numerous folds and villi. The synovial membrane is composed of inner layer of 1-4 cell thick synoviocytes and outer layer of loose vascular connective tissue.

## The structure of the joints consists of:

[1] **Soft tissues:** 

Joint space	- Join	t spac	e conta	ins articula	r car	tilage	with th	nin f	lim of
	syn	ovial f	luid.						
Joint capsule and ligaments	- The	size of	the cape	sule varies	as pei	the joi	int invo	lved	,
	small joints have close filling joint capsules, but larger								
joints like knee and hip have larger joints capsule.									
Periarticular tissue	-The	soft	tissue	covering	the	perio	steum	is	called
periarticular soft tissue.									

## [2] Bone ends

 In adults it consists of sub articular cortex, joint margin and Medulla and In younger age group it consists of Epiphysis and diaphysis

## [3] Structure of synovial joints:

The majority of joints in our body are synovial joints. In this type, the bone ends are not directly connected by any tissue. They have smooth articular surface covered by a layer of hyaline cartilage. Two bones are held together by a capsule made up of fibrous tissue. The capsule encloses the articular surfaces within a joint cavity. The capsule is lined by a synovial membrane which secretes a synovial fluid that acts as a lubricating agent and provides nourishment to the articular cartilage.

# **CLASSIFICATION OF JOINTS**

Cartilaginous	
(synchondroses and symphyeses)	<ul> <li>Partially movable jonts.</li> </ul>
Fibrous (synarthrodial)	– Immovable joints found in cranial vault and teeth.
Synovial joints ( diarthrosis)	- Freely movable joints are the most common joints
	found in the skeleton.

## Cartilaginous (synchondroses and symphyeses)

a. Synchondroses : Eg. Costal cartilage - sternum

b. Symphyses: Eg. Pubic symphysis.

## **Fibrous (synarthrodial)**

a. Suture	–E.g.Skull
b. Gomphoses	-E.g Alveoli/Teeth
c. Syndesmoses	– E.g Tibiofibular ligament

# Synovial joints (diarthrosis)

# a. Uniaxial joints

- Pivot joint (neck, atlas and axis bones, Radio-ulna joint)
- Hinge joint ( elbow and knee)

## **b.** Biaxial joints

- Condoler joint ( wrist)
- ✤ Saddle joint ( thumb)

# c. Multi axial joints

- Gliding joint (intercarpal, Between vertebrae in spine)
- Ball and socket joint ( shoulder and hip)

# ARTHRITIS

## **Definition:**

Arthritis means inflammation of joints

## Characteristic features of arthritis:

- Inflammation of the Joint
- Pain
- Redness
- Increased warmth
- Stiffness
- Swelling( major and minor joints)
- Fluid accumulation (synovial effusion)
- degenerative changes
- Resulting from infection,
- Metabolic disturbances or other causes.

# **Types of arthritis:**

- Osteoarthritis
- Rheumatoid arthritis
- Gout and Pseudo-gout
- Septic arthritis
- Juvenile idiopathic arthritis
- Ankylosing spondylitis
- Still's disease

# **RHEUMATOID ARTHRITIS (RA)**

Rheumatoid Arthritis is an autoimmune disease that results in a chronic, systemic inflammatory disorder of unknown causes. It may affect many tissues and organs, but principally attacks flexible (synovial) joints usually with a symmetrical distribution, It can be a disabling and painful condition, which can lead to substantial loss of functioning and mobility if not adequately treated. Its systemic manifestations include hematologic, pulmonary, neurological and cardiovascular abnormalities.

The name Rheumatoid arthritis originates from the Greek word

<u>Rheuma</u> = "that which flows as a river or stream," Oid = like or resembling Arthritis = Inflammation of joints.

- The name is based on the term "rheumatic fever", an illness which includes joint pain and is derived from the Greek word *rheuma (nom.), -rheumatos (gen.)* ("flow, current"). The suffix *-oid* ("resembling") gives the translation as *joint inflammation that resembles rheumatic fever*.
- The first recognized description of RA was in 1800 by the French physician Dr. Augustin Jocob Landre-Beauvais (1772 -1840) who was based in the famed Salpetriere Hospital in Paris.
- The name "Rheumatoid Arthritis" itself was coined in 1859 by British Rheumatologist Dr Alfred Baring Garrod.

# PREVALENCE

- The prevalence of rheumatoid arthritis in most Caucasian populations approaches 1% of adults and increases with age, approaching 2% in men and 5% in women, respectively.
- > The incidence also increases with age, peaking between the 4th and 6th decades.
- > The annual incidence for all adults has been estimated at 67 per 100,000.
- About 1% of the world's population is affected by rheumatoid arthritis, women three times more often than men. The incidence of RA is of 3 cases per 10,000 populations per annum. Onset is uncommon under the age of 15 and from then on the incidence rises with age until the age of 80  $^{(1)}$ .
- In India a local survey in Delhi shows the prevalence of this disease affecting 0.75% of population<sup>(2)</sup>.
- Around 40% of RA patients are registered disabled within 3 years; around 80% are moderately to severely disabled within 20 years; and 25% will require a large joint replacement <sup>(1)</sup>.
- ▶ It is 4 times more common in smokers than non-smokers.
- Family history is an important risk factor because It is strongly associated with the inherited tissue type Major histo compatibility complex (MHC) antigen HLA-DR4 (most specifically DR0401 usually in Indian patients and 0404)

▶ 80% affected are women. Male: Female ratio is 1:3.

## **ONSET:**

Mostly its onset is insidious and slow onset varying from weeks to months .In some people it is acute or sub acute onset.

# PATTERNS OF ONSET ON RHEUMATOID ARTHRITIS.

Insidious - 75%	Acute -15%	Sub acute -10%
Monoarticular - 20%	Palindromic -5%	
Oligo articular - 45%	Poly articular -35%	

## **CLINICAL COURSE**

Rheumatoid arthritis is usually life long with intermittent exacerbations and remissions.

## CAUSES

The exact causes of RA are unknown. But research has shown that several factors may contribute to the development of RA.

## **Antigenic agents:**

In which probably act as predisposing factors are Epstein bar, rubella, viruses etc, Genetic, psychological stress, endocrine factors, metabolic factors and allergic factors may also play a role.

## Genetic

Certain genes play a role in the immune system - for some people, genetic factors may be involved in determining whether they will develop RA. It is associated with Class II major histocompatability complex allele HLA-DR4 and HLA-DRB1

- ✤ HLA-DR4 gene 50 to 75 % (Severe deformities)
- HLA-DRB1 gene Common in Indian patients.

# **ENVIRONMENTAL RISK FACTORS:**

Life style factors:

- ✓ Obesity is a risk factor for Rheumatoid arthritis
- ✓ Smoking is a major environmental risk factor for developing Rheumatoid arthritis

- $\checkmark$  Alcohol cuts the risk most in smokers with genetic risk factors for RA
- ✓ There are complex interactions between the female sex hormones and Rheumatoid arthritis
- ✓ Coffee drinkers seems to be at increased risk of developing Rheumatoid arthritis
- ✓ The oral contraceptive pill or some other factor associated with its use appears to protect against the development of severe Rheumatoid arthritis
- ✓ Stress aggravates this disease

# **TRIGGERING FACTORS:**

- Viral infections Hepatitis B, Hepatitis C, Epstein Barr Virus and others.
- **Bacterial infections** Shigella, salmonella, group A Streptococcal ,Mycobacterium tuberculosis.
- Drugs, Toxins, UV light, vaccination, physical trauma.

# **CLINICAL FEATURES**

- Morning stiffness for at least one hour and present for at least six weeks.
- Swelling of three or more joints for at least six weeks.
- Swelling of major and minor joints like wrist joints, Metacarpophalangeal joints or proximal interphalangeal joints for at least six weeks.
- Symmetrical joint swelling.
- Low grade fever.
- Fatigue
- Anorexia
- Depression
- Changes in appearance of the joints (Spindle shaped appearance of fingers, Rheumatoid nodules, Swan neck deformity, Button hole deformity)

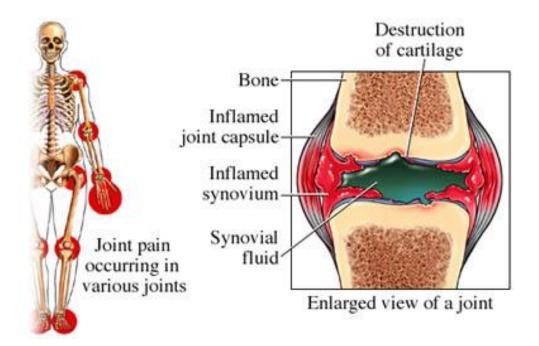
# INVOLVEMENT OF INDIVIDUAL JOINTS

Meta Carpo Phalangeal /Meta Tarso phalangeal

/Proximal Inter Phalangeal joints	-	90%
Knee, ankle and Wrist	-	80%
Shoulder joint	-	60%
Hip, elbow, acromion	-	50%

Cervical spine	-	40%
Temporomandibular & Sternomastoid joints	-	30%
Cricoartenoid joint	-	10%

**Commonly involved joints:** Finger joint (Meta Carpo Phalangeal /Meta Tarso phalangeal /Proximal Inter Phalangeal joints ), Shoulder joint, and Foot joint.



# HAND DEFORMITIES IN RHEUMATOID ARTHRITIS

- Swan neck deformity
- Button hole deformity or Boutonniere's deformity.
- Z deformity or hitch
- Morant baker's cyst
- Ulnar deviation of hand
- Trigger finger
- Equinus deformity

## SWAN NECK DEFORMITY

Hyperextention of Proximal Inter Phalangeal joints with flextion of Distal Inter Phalangeal joints.



## **BUTTON HOLE DEFORMITY OR BOUTONNIERE'S DEFORMITY**

Hyperextension of Distal Inter Phalangeal (DIP) and Meta Carpo Phalangeal (MCP) joints with flexion of Proximal Inter Phalangeal (PIP) joints



# .Z DEFORMITY OF THUMP OR HITCH

Severe hyperextension of the inter phalangeal joint of thumb with flexion of Meta Carpo Phalangeal (MCP) joint



#### **ULNAR DEVIATION OF HAND:**

Ulnar deviation or ulnar drift, it is a deformity of the hands in which the meta carpo phalangeal (MCP)joints bends or deviate towards the little finger.



## **TRIGGER FINGER**

Also known as Stenosing tenosynovitis, it is an inflammation of synovial sheath that encloses the flexor tendons of the thumb and fingers. it may result from enlargement of tendon itself or narrowing of 1 st annular pulley.



## **SHOULDER JOINT:**

The shoulder can not be moved, forward, backward in rotation. Difficulty in dressing, combing hair, eating, may be produced. It may lead to the formation of frozen shoulder.

## **OTHER DEFORMITIES (OR) FETURES**

## ANKLE AND KNEE JOINTS

- Hallus valgus
- Claw toes
- Hammer toes
- Over- riding of 2 and 3 toes
- Flattening of longitudinal arch,
- Prominent metatarsal head
- Excessive plantar tilt of meta tarsals
- Rheumatoid nodules
- Achilles tendinitis
- Calcaneal erosions.

## HALLUS VALGUS

Also known as **bunion**, is when there is a medial deviation of the 1 st metatarsal and lateral deviation of the great toe (hallux).



# **CLAW TOES**

It is characterized by hyper extension of Meta Tarso Phalangeal joint and flexion of Inter Phalangeal joint, except big toe.



## HAMMER TOES

Hammer toe or contracted toe is a deformity of Proximal Inter Phalangeal joint of the second, third, or fourth

Toe causing it to be permanently bent, resembling hammer.



## **EQUINUS DEFORMITY**

• Decreased ankle dorsiflexion duo to gastrocnemius contracture.

## PATHOLOLGY OF RHEUMATOID ARTHRITIS

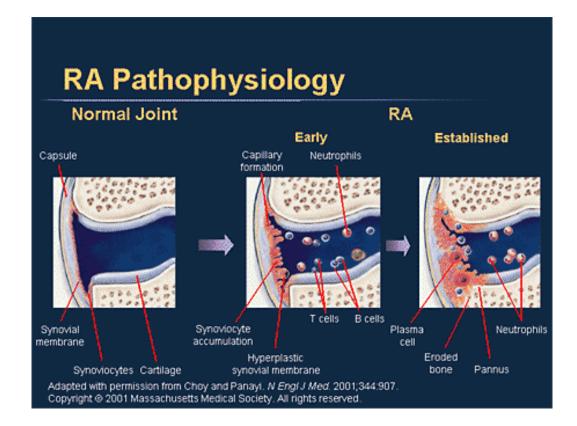
Synovial tissues are the primary target of auto immune inflammatory process in Rheumatoid arthritis.

The following changes occurs in synovial tissues

- Proliferation of Tcells ,B cells, macrophages, synovial cells in synovium.
- Production of excess amount of pannus and infiltration of pannus which results in synovitis.
- Destruction of cartilage and bones associated with tendons and ligaments occurs
- As a result signs and symptoms of rheumatoid occurs.

## STAGES IN PATHOLOLGY OF RHEUMATOID ARTHRITIS

- I. Pathology of Joints and Tendons.
- II. Pathology of Extra-articular tissues.



# I. PATHOLOGY OF JOINTS AND TENDONS

## It can be explained in three stages.

- 1. Synovitis.
- 2. Destruction.
- 3. Deformity.

## **1. SYNOVITIS**

Initial lesion occurs in the synovium, leading on to vascular stasis, and infiltration of the sub synovial layers with inflammatory cells and formation of fibrinous exudates. Synovial hypertrophy occurs with the thickening of capsular structures.

Though this stage is painful, tender and swollen, their structures are still intact and mobile. So, these disorders are reversibly potential.

## **2.DESTRUCTION:**

### **Pannus formation:**

Hypertrophied synovium along with granulation tissue leads to formation of pannus which encroaches the articular from its periphery.

## Articular cartilage:

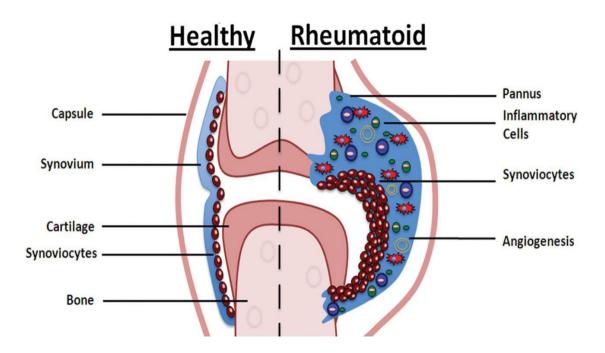
The articular cartilage gets destroyed gradually. Further the bony surface is involved, leading to obliteration of joint face. Joint get destroyed and deformed.

## **3. DEFORMITY:**

The extending granular pannus gets into fibrous tissue, bone, which leads to fibrous ankylosis and later bony ankylosis.

Muscles, tendons, and soft tissues around the joint also undergo inflammatory changes and get contracted or ruptured.

Juxta-articular osteoporosis occurs, Not all patients progress through all three stages.



## **EXTRA – ARTICULAR MANIFESTATIONS – COMPLICATIONS**

### • SYSTEMIC:

Weight loss Fatigue Susceptibility of infection

#### • VASCULITIS:

Digital arteritis Pyoderma gangrenosum Ulcers

## • HAEMATOLOGICAL:

Anaemia Thrombocytosis Eosinophilia Mononeuritis multiplex Visceral arteritis

# • MUSCULOSKELETEL:

Muscle Wasting Tenosynovitis Bursitis Osteoporosis

## • LYMPHATIC:

Spleenomegaly Lymphadenopathy Felty's syndrome

# • OCCULAR:

Episcleritis Scleritis Scleromalacia Kerato conjunctivitis sicca

## • CARDIAC:

Pericarditis Myocarditis Endocarditis Conduction defects Coronary vasculitis Granulomatous arthritis

## • PULMONARY:

Nodules Pleural effusion Fibrosing alveolitis Bronchiolitis

## • **NEUROLOGICAL:**

Cervical Cord compression Compression neuropathies Peripheral neuropathy Mononeuritis multiplex Amyloidosis

## • NODULES:

Sinuses Fistula

### DIAGNOSIS

## I.CRITERIA FOR DIAGNOSING RHEUMATOID ARTHRITIS

(American Rheumatism Association 1988)

- Morning stiffness more than 1 hour for more than 6 weeks.
- Arthritis of three or more joints for more than 6 weeks.
- Arthritis of hand joints (wrist, MCP or PIP joints.) for more than 6 weeks.
- Symmetrical arthritis, at least one area lasting for 6 weeks.
- Rheumatoid factor.
- Rheumatoid nodules.
- Radiological changes.
- Duration of 6 weeks or more.

Diagnosis of Rheumatoid Arthritis is made with 4 or more criteria

# LABORATORY INVESTIGATIONS 1.BLOOD

#### **Complete Blood Count**

Haemoglobin	-	Anaemia
Thrombocytes	-	Thrombocytosis
ESR	-	Increased
Serum proteins:		
Albumin	-	Decreased
Gamma globulin	-	Increased
IgG, IgM, IgA	-	Increased

#### 2. SEROLOGICAL TESTS

## a) RHEUMATOID FACTOR

Rheumatoid factor measures how many of one type of antibodies (IgM, sometimes IgA) binds to a second type of your antibodies (IgG). Initially, only one third of people with RA test positive for the set of antibody called the Rheumatoid Factor (RF).

Most people with Rheumatoid Arthritis will eventually develop this marker and a positive RF is considered a sign and symptom of rheumatoid arthritis. However, some people test positive for rheumatoid factor, yet never develop the disease.

#### b) ANTI-CCP

These anti-CCP antibodies bind to some self proteins that are found predominately in the synovial tissue. The citrullinated proteins include filaggrin and its circular form (cyclic citrullinated peptide: CCP). The presence of these antibodies often correlates with some joint destruction. Although this test is relatively recent, a high level of anti-CCP is considered a sign and symptom of Rheumatoid Arthritis.

#### c) ERYTHROCYTE SEDIMENTATION RATE

It measures the quantity and how quickly the cells are pelleted by spinning in a centrifuge. Indirectly, it measures how many cells are bigger and thus activated.

#### d) C-REACTIVE PROTEIN

A higher than normal level of C-reactive protein (CRP) in the blood also indicates that your body has chronic inflammation, and is a common sign and symptom of Rheumatoid Arthritis.

### **3.RADIOLOGY: X-rays**

#### Early changes

Soft tissue swelling Peri articular osteoporosis Erosions-Peri articular and sub articular cysts

#### Late changes

- Articular surface irregularity Osteoporosis Subluxation Ankylosis Secondary Osteoarthritis
- 4. ULTRASOUND: Soft tissue abnormalities, e.g. synovial cysts.
- 5. CT SCAN, MRI: Much greater information of bone, joint and soft tissue.

### 6. ARTHROSCOPY

- Direct view of joint and synovial fluid.
- Potential for biopsy and therapeutic procedures.

## 7. SYNOVIAL FLUID

- White cell count raised in infection.
- Crystal identification: Presence of Urate, Calcium pyrophosphate, crystals present.
- Synovial fluid analysis confirms the presence of inflammatory arthritis.

## 8.BIOPSY

Synovial biopsy : Villu formation with thickening of synovial layer and infiltration with abnormal cells.

# **DIFFERENTIAL DIAGNOSIS**

Several other medical conditions can resemble RA, and usually need to be distinguished from it at the time of diagnosis.

## Systemic Lupus Erythematosus (SLE)

Distinguished by specific clinical symptoms and blood tests.

- Anti Nuclear Antibody (ANA) titre
- Anti-DNA
- Complement fixation decreased
- ESR increased
- Complete Blood Count, Urine Analysis
- Kidney biopsy

## Crystal Induced arthritis (Gout, and Pseudo gout)

- It usually involves particular joints (knee, Meta tarsal phalanges, heels)
- It can be distinguished with aspiration of joint fluid if in doubt. Redness (RA doesn't have redness at the joints),
- Asymmetric distribution of affected joints,
- Pain occurs at night and the starting pain is less than an hour with gout.

## **Osteoarthritis :**

Due to "wear and tear", develops slowly in Middle-aged and elderly

- Late joint changes,
- bony sclerosis,
- minimal inflammation,
- Synovial fluid increased,
- spur formation
- Gait analysis

## **Psoriatic arthritis:**

Resembles RA, skin symptoms and nail changes distinguish between them.

#### **Reactive Arthritis (previously Reiter's disease)**

Asymmetrically involves heel, sacroiliac joints, and large joints of the leg. It is usually associated with urethritis, conjunctivitis, iritis, painless buccal ulcers, and keratoderma blennorrhagica.

#### Ankylosing spondylitis:

This involves the spine, although a RA-like symmetrical small-joint polyarthritis may occur in the context of this condition.

### Hepatitis C :

Hepatitis C may also induce Rheumatoid Factor auto-antibodies.

#### Sarcoidosis, Amyloidosis and Whipple's disease can also resemble RA.

#### Hemochromatosis

May cause hand joint arthritis.

#### Acute Rheumatic fever

It can be differentiated from RA by a migratory pattern of joint involvement and evidence of antecedent streptococcal infection. Bacterial arthritis (such as streptococcus ) is usually asymmetric. While RA usually involves symmetrical joints.

The Study on VALIAZHAL KEELVAYU was carried out in the OPD and IPD of the Maruthuvam department, National Institute of Siddha, Chennai.

The trial drug "MERUGULLI THYLAM"(Internal) was indicated in the authorised Siddha text Theraiyar Thylavarga Surukkam, P.NO 80-81 for VALIAZHAL KEELVAYU.

## **STUDY DESIGN**

An open Clinical trial

## STUDY PLACE

OPD and IPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47.

## **STUDY PERIOD**

November 2015-2018 October

## SAMPLE SIZE

40 patients, 39 cases were treated in OPD and one case was admitted in IPD and the trial drug was given.

## TRIAL DRUG

#### **INTERNAL MEDICINE**

Drug	:	Merugulli thylam
Dosage	:	kaal balam-9 grams (9 ml)-3 days morning only(2 days drug
		holiday)
Duration	:	45 days
Reference	:	Theraiyar Thylavarga Surukkam
Publication	:	B. Rathna Nayakar & Sons.
Author	:	T.C.Subbramaniya Pandither
Page No.	:	80-81
Edition	:	11 <sup>th</sup> edition, 2012.

#### Source of raw drugs

The required raw drugs for preparation of "*Merugulli thylam*" (Internal) were purchased from a well reputed country shop and the purchased drugs were authenticated by Assistant professor of the Medicinal botany at National Institute of Siddha, Chennai.

#### **Drug Storage**

*Merugulli thylam* was stored in a clean and narrow mouthed glass bottles.

#### **Dispensing:**

The Internal medicine (9 ml) was distributed in Disposable pet bottles.

## SUBJECT SELECTION

Patients reporting to NIS were subjected to screening by screening Proforma. After screening they were enrolled for the study fulfilling the inclusion criteria as said below.

#### **Inclusion Criteria**

- Age: 20- 60 years.
- Both male and female.
- Symmetrical joint involvement at least one joint for more than 6 weeks
- Arthritis of three or more joints for more than 6 weeks
- Swelling present in major and minor joints especially in the inter-phalangeal joint.
- Rheumatoid factor positive or negative.
- Morning stiffness for more than one hour for more than 6 weeks
- Deformities like Button hole deformity and Swan neck deformity, spindle shaped deformity etc.
- Anti CCP positive.
- American criteria for rheumatoid arthritis were followed.
- Patients willing for admission and stay in IPD or willing to attend OPD.
- Patient willing to undergo Radiological investigation and for laboratory investigation.
- Patient willing to sign the informed consent stating that he/she was consciously stick to the treatment during 45days but could opt out of the trial of his/her own conscious discretion.

## **Exclusion Criteria**

- Pregnancy and lactation
- Tubercular arthritis
- Any other serious systemic illness like cancer, Cardiac Disease
- Osteoarthritis
- Psoriatic arthritis
- Gouty arthritis
- Diabetic Mellitus
- Hypertension
- Thyroidism (Hypo/hyper)

## Withdrawal Criteria

- Intolerance to the drug and development of adverse reactions during the trial.
- Poor patient compliance and defaulters.
- Patient turned unwilling to continue in the course of clinical trial.

### **Tests and Assessments**

- A. Clinical assessment
- B. Siddha investigation
- C. Laboratory investigations
- D. Radiological investigation

## A. Clinical Assessment

- Arthritis involving three or more joints
- Symmetrical joint involvement
- Morning stiffness
- ✤ Anorexia
- Spindle shaped appearance of fingers
- Rheumatoid nodules
- Depression
- Swelling of small joints of hands and foot.
- Swan neck deformity
- Button hole deformity

## **B. Siddha System Examination**

- 1. Naadi
- 2. Sparisam
- 3. Naa
- 4. Niram
- 5. Mozhi
- 6. Vizhi
- 7. Malam
- 8. Moothiram
  - a. Neer kuri
- Niram colour
- Edai Specific gravity
- Manam- Smell
- Enjal Deposits/quantity urine voided.

b.Neikuri:

- When the oil drops lenthens like a snake it indicates 'Vatha Neer'
- When the oil drops Spreads like a ring it indicates 'Pitha Neer'
- When the oil drops Remains that of pearl it indicates 'Kaba Neer'

## C. ROUTINE INVESTIGATIONS

## BLOOD

Hb

Total WBC Count

DC- Polymorphs

- 1. Lymphocytes
- 2. Eosinophils
- 3. Monocytes
- 4. Basophils

Total RBC count

ESR

<sup>1</sup>/<sub>2</sub> Hr: 1 Hr:

Blood sugar

Fasting: PP:

Serum cholesterol

#### URINE

Albumin Sugar (F) (PP) Deposits

## **Renal function tests**

Blood Urea Uria acid Serum Creatinine

## Liver function tests

Serum Total bilirubin Direct bilirubin Indirect bilirubin Serum Alkaline phosphatases SGOT SGPT

## **D. SPECIFIC INVESTIGATIONS**

CRP RA factor ASO Titre

# E. RADIOLOGICAL INVESTIGATIONS

X-Ray of affected joints (AP and Lat view)

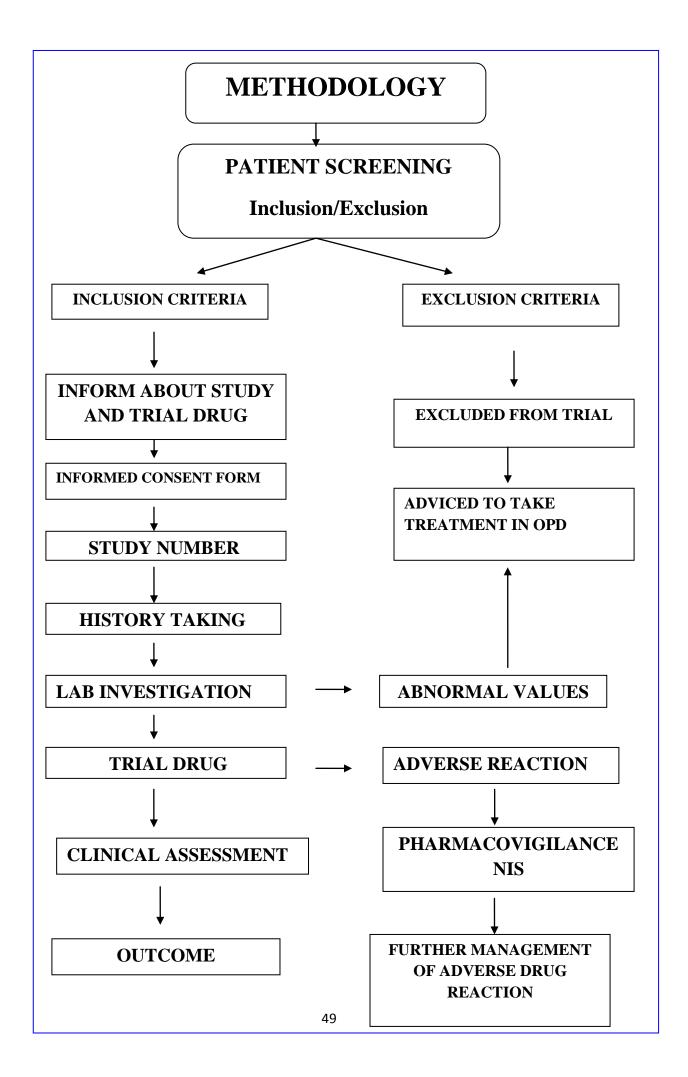
## G. DATA COLLECTION FORMS:

Required information was collected from each patient by using following forms.

## FORMS

FORM I	:	Screening and Selection Proforma
FORM II	:	History Taking And Clinical Assesment Proforma
FORM III	:	Laboratory Investigation form
FORM IV	:	Drug Compliance form

FORM V	:	Patient Information Sheet
FORM VI	:	Informed Consent Form
FORM VII	:	Withdrawal Form
<u>FORM</u> VII-B	:	Adverse Drug Reaction (or) Pharmacovigilance form
FORM VIII	:	Dietary form



#### METHODOLOGY

#### STUDY ENROLLMENT

After registered in CTRI (Clinical Trials Registry-India) the patients were enrolled for the study.

#### CTRI NO: CTRI/2018/03/012365

Patients reporting at the OPD of NIS with the clinical symptoms of Vali Azhal Keelvayu were examined clinically. Based on the inclusion and exclusion criteria, they were enrolled for the study.

The patients who were enrolled were informed about the study, trial drug, possible objectives and outcomes of the study in their vernacular language. After ascertaining the patient's willingness, informed consent were obtained in concent form.

Complete clinical history, complaints and duration, examination findings and laboratory findings were recorded in the prescribed Proformas. Patients were advised to take the trial drug and appropriate dietary advice.

#### **CONDUCT OF THE STUDY**

The trial drug *Merugulli thylam* (Internal) was given for 45 days. OPD patients were asked to visit the hospital once in 5 days. At each clinical visit clinical assessment was done and prognosis was noted. For IPD patient the clinical assessment was done daily. The results were compared at the end of the study. Laboratory investigations and radiological investigation was done before and after trail. At the end of the treatment, the patients were advised to visit the OPD without trail drug for follow-up for further 2 months for observing any recurrence. Defaulters were not been allowed to continue and be withdrawn from the study.

### DATA MANAGEMENT

After enrolling the patient in the study, separate files were maintained for each and every patient and all forms and other information were kept in the file. The screening forms were filed separately. The data entries were monitored by the Head of the department, Maruthuvam. All collected data were statistically analyzed by Senior Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results was permitted for unbiased reports. Then final report was generated.

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#### STATISTICAL ANALYSIS

All the data were entered into computer using MS access software for logical errors and manually cross checked for data entry error. Then the data was explored to STATAL/SPSS software for univariate /multivariate analysis. Student 't' test and paired 't' test and Mantel-Haenszel chi-square test was performed for determining the significance of a particular effect variable.

### OUTCOME

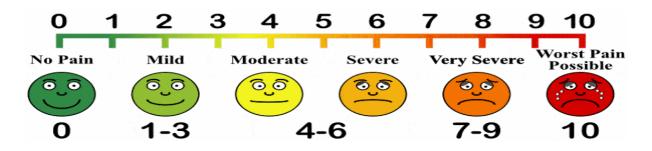
## PRIMARY OUTCOME

Assessment of pain was by Universal pain assessment scale. Other clinical signs and symptoms were assessed by Gradation method.

#### SECONDARY OUTCOME

Laboratory investigations such as RA factor, CRP, ASO titre, were also be done at the end of the study.

#### UNIVERSAL PAIN ASSESMENT SCALE



Grade 0	: No Pain
Grade 0	. NO Palli

Grade 1-3 : Mild pain

Grade 4-6 : Moderate pain

Grade 7-10 : Severe pain

- Ref: Clinical Manual for Nursing Practise (National Institute of Health Warren Grant Magnuson Clinical Centre )

#### Restricted movements is assessed by the following Gradation,

Grade 1	<ul> <li>Able to perform normal duties</li> </ul>
Grade II	- Moderate Restriction - Self care is possible
Grade III	- Marked restriction - Limited self care/some assistance required.
Grade IV	- Confined to bed or wheel chair

#### **ADVERSE EFFECTS/ SERIOUS EFFECTS MANAGEMENT**

If the trial patient developed any adverse reaction, he/she would be immediately informed to the Pharmaco-vigilance committee of NIS for further management.

## ETHICAL ISSUES

- 1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipments were used.
- 2. The patients were informed about the treatment and other procedures in his/her vernacular language. After received written consent only (language understandable to the patient) they were enrolled in the study.
- 3. The data collected from the patient were kept confidential.
- 4. No other external or internal medicines were used, other than the trial drug during the trial period. There was no infringement on the rights of the patient.
- 5. Treatment were provided free of cost.
- 6. For those tests which are performed in outside lab the money should be borne by the patients.
- 7. If any serious adverse reactions occur during trial, the patients were given alternative treatment at regular OPD of National Institute of Siddha.
- 8. If the patient was not willing to continue the treatment, he/she was allowed to withdrawed from the trial at any time.

#### PURIFICATION OF RAW DRUGS

#### 1.Merugan kizhangu (Alocasia indica.Schott)

Removed the skin of merugan kizhangu and cut into small pieces & dried. *Ref:Theraiyar thylavarka surukkam. P.no:80* 

#### 2.Bulb of Garlic (Allium sativum.Linn)

Peeled and cleaned the outer layer of garlic

Ref: Theraiyar thylavarka surukkam.P.no:80

#### **3.**Castor oil (*Ricinus communis*)

Castor oil was taken in a bottle and 1/4 th of the glass bottle was kept under the sand. Then it was under sun shade for 2 days and the filtrate was taken

Ref:Sigicha rathna theebam ennum vaithiya nool.P.no:27

## Internal medicine – Merugulli thylam:

#### **Ingredients:**

1.Merugan kizhangu (*Alocasia indica.Schott*) Equal quantity

2. Garlic (Allium sativum.Linn)

3. Caster oil(Ricinus communis.Linn)= Equal quantity of 1 and 2

## **METHOD OF PREPARATION**

Peeled and cleaned skin of the merugan tuberous stem and garlic and cut into small pieces, then it grinded into a paste. Heat the paste with castor oil boiled until it reached a wax consistency. Then filtered and took the oil. Used after 3 days.

#### **Drug Storage:**

Merugulli thylam was stored in a clean and narrow mouthed glass bottles.

#### **Dispensing:**

The Internal medicine (9 ml) was given in Disposable pet bottles.

#### **PROPERTIES OF THE INGREDIENTS OF TRIAL DRUGS**

1. Merugan kizhangu (Alocasia indica.Schott)

English name	:	Great leaved caladium , Giant taro, ape.
Botanical name	:	Alocasia indica.Schott
Family	:	Araceae
Parts used	:	Tuber
Constituents	:	Alomacrorrhiza A and allocasin, ascorbic acid.
Organoleptic Charac	ters	
Taste	:	Kaarppu
Potency	:	Veppam
Pirivu	:	Kaarppu
Therapeutic actions	:	Anti-inflammatory
		Antinociceptive
		Antioxidant
		Analgesic activity

Therapeutic effects

மெருகங் கிழங்கு அரச னமைச்ச னதிகாரி சேனைக் கரச னிவர்க்கிகலே யாகிப்-பொருவும் மிருகமெனு நாயைமுயல் மேல்விடு தல்போல் மெருகடியை யேவுவினை மேல்.

#### (தேரன்-வெண்பா)

The analgesic and anti-inflammatory activities of the crude ethanolic extract of dried rhizome of Alocasia indica (Roxb.) Schott <sup>(9)</sup>.

The detoxified tuber is used to treat influenza, high fever and malaria; diarrhea and typhoid fever, rheumatic; pulmonary tuberculosis and tuberculous lymphadenopathy; headache; abscesses and ring worms <sup>(10)</sup>.

Alocasia indica Schott had ascorbic acid anti-inflammatory, antinociceptive activities and antioxidant property  $^{(11)}$ .

### 2.Bulb of Garlic (Allium sativum.Linn)

English name	:	Garlic		
Botanical name	:	Allium sativum.Linn		
Family	:	Amaryllidaceae		
Parts used	:	Bulb		
Constituents	:	Alliin, tryptophan, sativioside, allyl methyl trisulphide,		
Scordinine A,,A1, A2 & B,Five saponins , n-3 fatty acids, indolic and phenolic compounds,				
5-hydroxy-l-tryptophan, in RAW 264.7 cells, organosulfur compounds, phenolic acids,				
allyl thiosulfinates, flavonoids, and vitamins etc				

**Organoleptic Characters** 

Taste	:	Kaarppu.
Potency	:	Veppam
Pirivu	:	Kaarppu
Therapeutic actions	:	Anti-inflammatory
		Antinociceptive
		Antioxidant
		Analgesic activity
		Antiarthritic activity
		Hypolipidemic
		Anticoagulant
		Anticancer
		Antigenotoxic,
		Anticlastogenic effects

Therapeutic effects

சன்னியொடு வாதந் தலைநோவு தாள்வலி மன்னிவரு நீர்க்கோவை வன்சீதம்- அன்னமே! உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம் வெள்ளுள்ளி தன்னால் வெருண்டு. (அகத்தியர் குணவாகடம்)

Alliin the precursor of the antibiotic principle of *Allium sativam* was found useful in the treatment of **rheumatoid arthritis.** A beneficial change in mucoprotein level and **ESR** was observed when clinically evaluated. It gives a significant effect such as pain relief, morning stiffness, swelling in patients with different rheumatic disorder<sup>(12)</sup>.

Allicin exhibits hypolipidemic, antiplatelet, and procirculatory effects. Moreover, it demonstrates antibacterial, anticancer, and chemopreventive activities. Allicin ((R, S)-diallyldisulfid-S-oxide), one of the sulfur compounds from garlic, is formed by the action of the enzyme alliinase on alliin. It possesses antioxidant activity <sup>(13)</sup>. Antioxidant and Antiarthritic Activity of Allicin were done in Animal Models <sup>(14)</sup>.

## CASTER OIL(Ricinus communis.Linn)

English name	:	Castor,Castor oil plant.
Botanical name	:	Ricinus communis.Linn
Family	:	Euphorbiaceae
Parts used	:	Root, leaf, Flower, seed, seed oil.
Constituents	:	Alkaloids, ricinine, albumin, ricin and 1-methyle-3-cyano-4-
methoxy-2-2pyridone, $\beta$ - stosterol, ricinine, Gallic acid, Flavonoid-lucenin, Hydro cyanic		

acid and uric acids (oil) etc.

### **Organoleptic Characters**

Taste	:	Kaarppu.
Potency	:	Veppam
Pirivu	:	Kaarppu
Therapeutic actions	:	Anti-inflammatory;
		Spasmogenic,
		Hepato protective,
		Anti fertility
		Purgative
		Imminizing
		CNS depressant,
		Spasmolytic.

#### **IN SIDDHA ASPECT**

ஆமணக் கெண்ணெய் தன்னை யணிநில மறியக் கேண்மின் பூமணச் சந்ததோறும் பொருந்திய வாதம் போக்கும் தீமந்தந் தானும் போக்குந் திகழ்வுடன் விரைவு முண்டாம் தீமனக் குடலில் வாதஞ் சேர்குட லேற்றம் போமே

#### (குணபாடம் - மூலிகை)

Seed oil-anti pyretic, recommended for abdominal disorders, dysentery, chronic articular rheumatism, oedema<sup>(15).</sup>

# MERUGAN KIZHANGU



# GARLIC



# **CASTER OIL**



# MERUGULLI THYLAM



# BIO -CHEMICAL ANALYSIS OF MERUGULLI THYLAM AT

# NATIONAL INSTITUTE OF SIDDHA

S.No	EXPERIMENT	OBSERVATION	INFERENCE
1.	Physical Appearance of sample	Dark brown in colour	
2.	<ul> <li>Solubility:</li> <li>a. A little of the sample is shaken</li> <li>well with distilled water.</li> <li>b. A little of the sample is shaken well</li> <li>with con. HCl / Con. H<sub>2</sub>So<sub>4</sub></li> </ul>	Sparingly soluble	Presence of Silicate
3.	Action of Heat: A small amount of the sample is taken in a dry test tube and heated gently at first and then strong.	No brown fumes	Absence of Nitrate
4.	Flame Test: A small amount of the sample is made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.	No Bluish green flame appeared.	Absence of Copper
5.	Ash Tests: A filter paper is soaked into a mixture of sample and cobalt nitrate solution and introduced into the Bunsen flame and ignited	No Yellow colour flame	Absence of sodium

## **Preparation of Extract:**

5gm of Merugulli thylam is weighed accurately and placed in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water.

S.No	EXPERIMENT	OBSERVATION	INFERENCE
	I. Test For Acid Radicals		
1.	Test For Sulphate:2ml of the above preparedextract is taken in a test tube tothis added 2ml of 4%ammonium oxalate solution.Test For Chloride:2ml of the above preparedextract is added with dil.Hno3 tillthe afferreserves access Then 2	No Cloudy appearance present No Cloudy	Absence of Sulphate Absence of Chloride
3.	the effervescence ceases. Then 2 ml of Silver nitrate solution is added .	appearance present	
5.	Test For Phosphate: 2ml of the extract is treated with 2ml of dil.ammonium molybdate solution and 2ml of con.HNo3	Cloudy yellow appearance present	Presence of Phosphate
4.	Test For Carbonate: 2ml of the extract is treated with 2mldil. magnesium sulphate solution	No Cloudy appearance present	Presence of Carbonate
С	Test For Nitrate: 1gm of the substance is heated with copper turning and con.H2So4 and viewed the test tube vertically down.	No Brown gas is evolved	Absence of Nitrate

	Test For Sulphide:		
6.	1gm of the substance is	No Rotten Egg Smelling gas evolved	Absence of Sulphide
	treated with 2ml of con. HCL		
7.	Test For Fluoride & Oxalate:		
	2ml of extract is added with	No Cloudy appearance	
	2ml of dil. Acetic acid & 2ml		Absence of fluoride
	dil. calcium chloride solution &		and oxalate
	heated.		
8.	Test For Nitrite:		
	3drops of the extract is placed	No Characteristic	
	on a filter paper, on that-2 drops		Absence of Nitrite
	of dil.acetic acid and 2 drops of	changes	
	dil. Benzidine solution is placed.		
	Test For Borate:		
	2 Pinches (50mg) of the		
	substance is made into paste by		
	using dil. sulphuric acid and	Bluish green colour	Absence of borate
	alcohol (95%) and introduced	flame not appeared	Absence of borate
	into the blue flame.		
	II. Test For Basic Radicals		
1.	Test For Lead:	No Yellow	
	2ml of the extract is added	Precipitate is	Absence of Lead
	with 2ml of dil. potassium iodine	obtained.	Absence of Lead
	solution.	ootumed.	
	Test For Copper:		
	<b>a.</b> One pinch(50mg) of substance	No Blue colour	
	is made into paste with con.	flame	Absence of copper
	HClin a watch glass and	No Blue colour	
	introduced into the non-	precipitate formed.	
	luminuous part of the flame.		
3.	Test For Aluminium:	No characteristic	
	To the 2ml of extract	changes	Absence of aluminium
	dil.sodium hydroxide is added in		

	5 drops to excess.		
4.	Test For Iron:a. To the 2ml of extract add 2mlof dil. ammonium solutionb. To the 2ml of extract 2mlthiocyanate solution and 2ml ofcon HNo3 is added	Blood Red colour appeared	Presence of Iron
5.	Test For Zinc: To 2ml of the extract dil.sodium hydroxide solution is added in 5 drops to excess and dil.ammonium chloride is added.	White precipitate is not formed	Absence of Zinc
6.	Test For Calcium:2ml of the extract is addedwith 2ml of 4% dil. ammoniumoxalate solution	Cloudy appearance and white precipitate is obtained	Presence of calcium
7.	Test For Magnesium:To 2ml of extract dil. sodiumhydroxide solution is added indrops to excess.	No White precipitate is obtained	Absence of Magnesium
8.	Test For Ammonium:To 2ml of extract 1 ml ofNessler's reagent and excess ofdil. sodium hydroxide solutionare added.	Brown colour appeared	Presence of ammonium
9.	Test For Potassium:Apinch(25mg)ofsubstance is treated of with 2mlofdil.sodiumofdil.sodiumnitritesolutionand then treated with 2ml ofdil.cobaltnitratecobaltnitratein30%dil.glacialaceticacid.	No Yellowish precipitate is obtained.	Absence of Potassium

10.	Test For Sodium:		
	2 pinches (50mg) of the	No Yellow colour	Absence of Sodium
	substance is made into paste by	flame appeared	
	using HCl and introduced into		
	the blue flame of Bunsen burner.		
11.	Test For Mercury:		
	2ml of the extract is treated	No yellow	
	with 2ml of dil. sodium	precipitate is	Absence of Mercury
	hydroxide solution.	obtained	
12.	Test For Arsenic:	No brownish red	Absence of Arsenic
	2ml of the extract is treated	precipitate is	
	with 2ml of dil. sodium	obtained	
	hydroxide solution.		
	III. Miscellaneous		
1.	Test For Starch:	Blue colour	Presence of starch
	2ml of extract is treated with	developed	
	weak dil. Iodine solution		
2.	Test For Reducing Sugar:		
	5ml of Benedict's qualitative		
	solution is taken in a test tube	No Brick red colour	Absence of reducing
	and allowed to boil for 2 minutes	is developed	sugar
	and added 8 to 10 drops of the		
	extract and again boil it for 2		
	minutes. The colour changes are		
	noted.		
3.	<b>Test For The Alkaloids</b> : a)2ml of the extract is treated	No Red colour	
	with 2ml of dil. potassium	developed	
	lodide solution.	Yellow colour	Presence of Alkaloid
	b) 2ml of the extract is treated with 2ml of dil. picric acid.	developed No White precipitate	
	c) 2ml of the extract is treated	developed	
	with 2ml of dil. phosphotungstic		
	acid.		

4.	Test For Tannic Acid:		
	2ml of extract is treated with	No black precipitate	Absence of Tannic acid
	2ml of dil. ferric chloride	is obtained	
	solution		
	Test For Unsaturated		
	Compound:	Potassium	Absence of unsaturated
	To the 2ml of extract 2ml of	permanganate is not	compound
	dil. Potassium permanganate	decolourised	
	solution is added.		
6.	Test For Amino Acid:		
	2 drops of the extract is placed	No Violet colour	Absence of amino
	on a filter paper and dried well.	developed	acids
	20ml of Biurette reagent is		
	added.		
7.	Test For Type Of Compound:	No green colour	Absence of oxy
	2ml of the extract is treated	Developed	quinole pinephrine and
	with 2 ml of dil.ferric chloride		pyro catechol.
	solution.	No red colour	Anti pyrine, Aliphatic
		developed	amino acids and
			meconic acid are
		No violet colour	absent
		developed	Apomorphine
		No blue colour	salicylate and
		developed	Resorcinol are absent
			Morphine, Phenol
			cresol and
			hydrouinoneare absent

# **BIO -CHEMICAL ANALYSIS**

S.NO	CONSITUENTS	INFERENCE
1.	Silicate	Present
2.	Iron	Present
3.	Alkaloids	Present
4.	Phosphate	Present
5.	Calcium	Present
6.	Ammonium	Present
7.	Starch	Present

#### **Standardization Report**

S.NO	PARAMETERS	RESULTS			
1	Refractive index	1.4752			
2	Acid value	9.41			
3	Saponification Value	181.45			
4	Peroxide Value	5.36			
5	Iodine value	83.11			
6	Weight	0.964			

### **Test for Aflatoxin**

The trial drug Merugulli thylam was free from Aflatoxins.

### **TEST FOR AFLATOXIN**

The procedures recommended for the detection of Aflatoxin as per WHO (2007).

### **Instrument Details:**

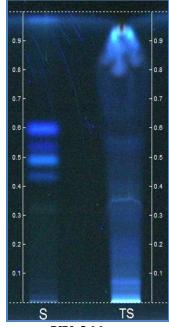
Name of the Instrument	: CAMAG (CAMAG - Automatic TLC sampler,				
	Scanner and Visualiser)				
Spray Gas	: N2				
Lamp used	: Mercury Lamp				

The samples were processed as per procedures recommended in WHO 2007 and applied for the Thin Layer Chromatography and High Performance Thin Layer Chromatography study with suitable solvent systems. After development the plate was allowed to dry in air and examined under 366nm.

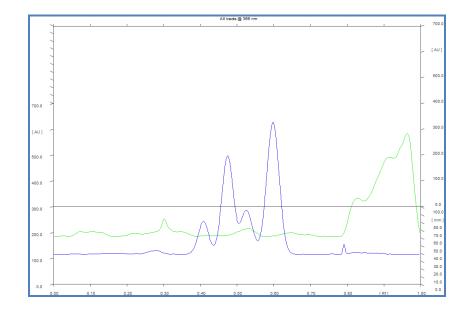
#### RESULTS

#### **TEST FOR AFLATOXIN ANALYSIS:**

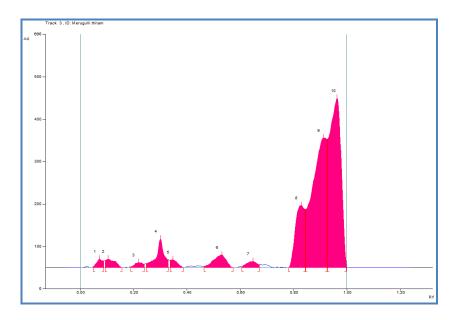
The sample TS: Merugulli thailam,  $15\mu$ l and Standard Std - G2, G1, B2 and B1 (20  $\mu$ l) were applied on TLC aluminium sheet silica gel 60 F 254 (E.MERCK) and plate was developed using the solvent system Chloroform : acetone : water (14 : 2 : 0.2). After development the plate was allowed to dry in air and examined under UV 366 nm



UV-366nm



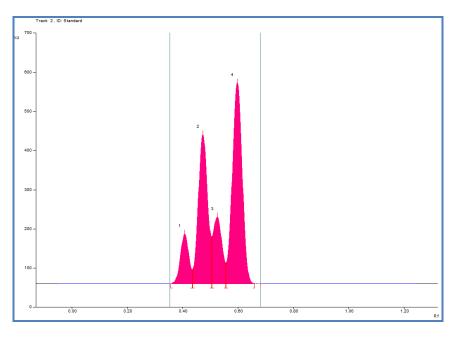
HPTLC Densitometric chromatogram (366nm) Test sample (TS) : Merugulli Thailam ; Standard (S) – G2, G1, B2 & B1



HPTLC finger print of Sample (TS) : Merugulli thailam at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.05 Rf	2.4 AU	0.07 Rf	20.5 AU	1.98 %	0.09 Rf	15.6 AU	336.9 AU	1.04 %
2	0.10 Rf	16.5 AU	0.10 Rf	20.1 AU	1.94 %	0.16 Rf	0.1 AU	512.0 AU	1.58 %
3	0.19 Rf	1.8 AU	0.22 Rf	11.7 AU	1.13 %	0.24 Rf	8.2 AU	272.5 AU	0.84 %
4	0.25 Rf	9.7 AU	0.30 Rf	68.3 AU	6.59 %	0.33 Rf	18.6 AU	1420.4 AU	4.39 %
5	0.34 Rf	17.7 AU	0.35 Rf	18.7 AU	1.81 %	0.39 Rf	0.1 AU	347.1 AU	1.07 %
6	0.46 Rf	3.2 AU	0.53 Rf	30.2 AU	2.91 %	0.57 Rf	0.3 AU	1036.3 AU	3.20 %
7	0.61 Rf	2.1 AU	0.65 Rf	15.1 AU	1.46 %	0.67 Rf	7.0 AU	420.0 AU	1.30 %
8	0.78 Rf	0.0 AU	0.83 Rf	146.9 AU	14.17 %	0.84 Rf	37.2 AU	3669.8 AU	11.33 %
9	0.85 Rf	137.4 AU	0.91 Rf	305.9 AU	29.51 %	0.93 Rf	02.6 AU	11790.3 AU	36.40 %
10	0.93 Rf	302.8 AU	0.96 Rf	399.2 AU	38.51 %	1.00 Rf	13.8 AU	12585.1 AU	38.85 %

Rf value of Sample (TS) : Merugulli thailam at 366nm



HPTLC finger print of Standard (S) at 366nm

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height		Area %
1	0.36 Rf	0.2 AU	0.41 Rf	127.8 AU	10.71 %	0.44 Rf	35.2 AU	2818.1 AU	9.58 %
2	0.44 Rf	36.4 AU	0.47 Rf	381.5 AU	31.96 %	0.50 Rf	19.8 AU	9345.2 AU	31.77 %
3	0.51 Rf	120.1 AU	0.53 Rf	170.8 AU	14.31 %	0.56 Rf	52.5 AU	3994.3 AU	13.58 %
4	0.56 Rf	53.8 AU	0.60 Rf	513.6 AU	43.02 %	0.66 Rf	0.6 AU	13254.9 AU	45.07 %

Rf value of Standard (S) at 366nm

फोन/Phone :044-26214823 फेक्स/Fax :044-26207566



ई-मेल/ E-mail: csmriasdd-chennai@gov.in

<u>csmdria@gmail.com</u> கேப்டன் சீனிவாசமூர்த்தி ஆயுர்வேத மண்டல மருந்தாக்க நிறுவனம் कैप्टन श्रीनिवासमूर्ति क्षेत्रीय आयुर्वेद औषध विकास संस्थान केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद, आयुष मंत्रालय, भारत सरकार,

ए. ए. सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नै-600 106

CAPTAIN SRINIVASA MURTHY REGIONAL AYURVEDA DRUG DEVELOPMENT INSTITUTE Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India, A.A Government Hospital Campus, Arumbakkam, Chennai: 600 106.

F.1-24/Test Reports/2018-19/CSMRADDI/

#### **TEST CERTIFICATE**

Customer's Name & Address

Dr. M. Suganthi, • NIS, Tambaram Sanatorium, Chennai - 47.

Your Lr. Dt. 26.04.2018

Ref. No.

Tests requested by customer

Lab. Method Used

- Peroxide value, Iodine Value, TLC, HPTLC and Weight 1. SOP: CSM/CL/022
- Ref: Indian Pharmacopeia, (IP) Vol.1,2014,P.203, 2.4.27 2. SOP: CSM/CL/023

Refractive Index, Acid value, Saponificaiton value, Iodine value,

- Ref: Indian Pharmacopeia, Vol.1, 2014, P.100, 2.3.23 3. SOP: CSM/CL/024
- Ref: Indian Pharmacopeia, Vol.1, 2014, P.109, 2.3.37 4. SOP:CSM/CL/026
- Ref: Indian Pharmacopeia, Vol.1, 2014, P.109, 2.3.35 5. SOP:CSM/CL/025
- Ref: Indian Pharmacopeia Vol.1, 2014, P.102, 2.3.28 6. SOP:CSM/CL/007
- Ref: Wagner, H. and Bladt, S. Plant Drug Analysis, A Thin Layer Chromatography Atlas IInd edition 1996.
  7. SOP:CSM/CL/008
- Ref: Dr. Sethi P.D. High Performance Thin Layer Chromatography Quantitative Analysis of Pharmaceutical formulations CBS Publisher and Distributors, Delhi, 1<sup>st</sup> edition 1996.
- 8. Not under NABL Scope Ref: API Appendix volume 2, 3, 4 appendix clauses 3.1.3. P.251

Report No

429/2018-19, dated 23/06/18

Technical Manager Name & Designation (252.04.V.Navasimhaje R.O. (chem.)

Quality Manager (Authorized Signatory)

### PART A: Particulars of Sample Submitted

a) Name of sample b) Grade /Variety/Type/Size/Class etc.	:	Merugalli Tailam
c) Declared values, if any	:	Tailam
d) Code No	:	Nil Nil
e) Batch No. and Date of manufacture	:	Nil
f) Quantity	÷	100 ml
g) Mode of packing	:	Plastic container
h) Seal	:	Sealed
i) Sample received on	:	26.04.2018
j) CSMDRIA Lab Code No.	:	1805427

### PART B: Supplementary Information

<ul><li>a) Reference to sampling procedure</li><li>b) Supporting documents for the measurements taken and results derived</li></ul>	: :	Drawn and supplied by customer Nil	
c ) Deviation from the test methods as prescribed in relevant ISS/Work Instructions, if any	:	Nil	

#### **Standardization Report**

S. No.	Parameters	Results
1	Refractive Index	1.4752
2	Acid Value	9.41
3	Saponification Value	181.45
4	Peroxide Value	5.36
5	Iodine Value	83.11
6	TLC	Report enclosed
7	HPTLC	Report enclosed
*0	W 1 . / 1	report enclosed

0.964

PART C: Test Results

Note: \*8 Not under Scope

Weight/ml

### PART D: Remarks

NB: 1. The results stated above relate only to the items tested.

- 2. This Test Certificate shall not be reproduced except in full without the written approval of the Laboratory.
- 3. The Test report shall not be utilized for any legal purpose without prior intimation to the issuing authority.

2018 Technical Manager

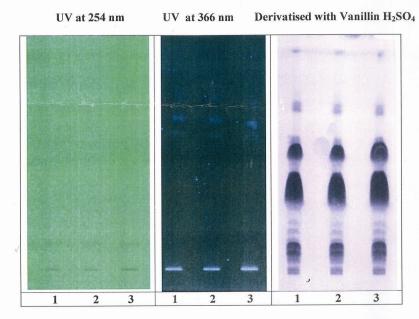
Name & Designation AS\_-CH.V. Nonasimhaye R. O. (Chem.)

\*8

Quality Manager (Authorized Signatory)

#### TLC/ HPTLC Identification of DTL- 1803427

TLC Photodocumentation of sample code – DTL 1803427



Track 1 & 2- Sample solution – 8 μl; Track 3- Sample solution - 12 μl; Solvent system : *Toluene : Ethylacetate:* (8.5: 1.5)

#### TLC Methodology:

0.3 g of oil dissolved with hexane and made up to 10 ml volumetric flask. The sample solution 8  $\mu$ l was applied on Tracks-1 &2, 12  $\mu$ l was applied on Tracks- 3 respectively on an E. Merck aluminium plate pre-coated with Silica gel 60F<sub>254</sub> of 0.2 mm thickness using ATS4 applicator. The plate was developed in the solvent system of *Toluene: Ethylacetate* (8.5: 1.5) upto 90 cm and dried. The plate was observed through CAMAG TLC Visualizer under UV at 254 nm and 366 nm photos were taken. Finally the plate was dipped in Vanillin-Sulphuric acid reagent and heated in hot air oven at 105°C untill the colour of the spots were appeared and photo was documented.

8- Jullio 22/6/18

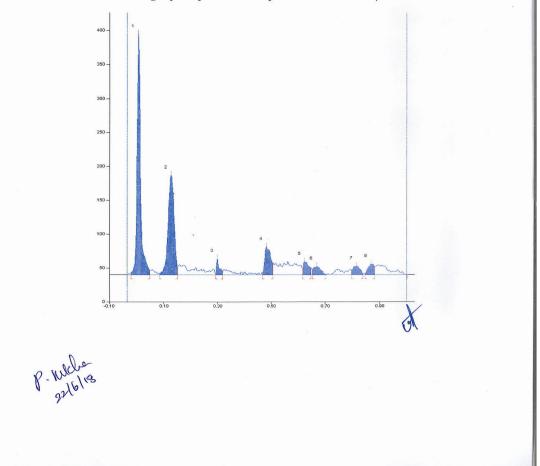
**Rf Values:** 

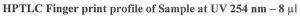
. . .

S. No	UV at 254	l nm	UV	at 366 nm	Derivatised with Vanillin-Sulphuric acid		
	$\mathbf{R}_{f}$	Color	$\mathbf{R}_{f}$	Color	R <sub>f</sub>	Color	
Track-1	0.12, 0.46,	Green	0.60,	Dull green	0.03, 0.06,	Grey	
Track-2 &	0.59		0.66,	Fluorescent blue	0.10, 0.13,	Dark Grey	
Track 3			0.75	Dull blue	0.15, 0.19, 0.23,	Grey	
					0.37, 0.54,	Dark Grey	
					0.60, 0.72, 0.75,	Grey	
					0.98	Grey	

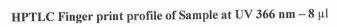
#### HPTLC Finger print profile of Sample code - 1805427

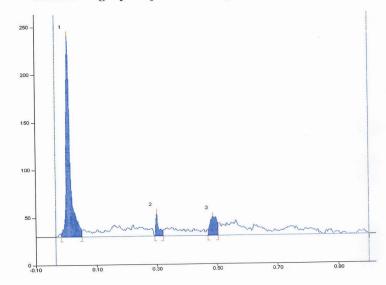
The TLC plate developed above was scanned at 254 nm and 366 nm using scanner 3, Camag HPTLC instrument using D2 lamp.





Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %	Assigned substance
1	-0.02 Rf	2.6 AU	0.00 Rf	354.9 AU	56.51 %	0.05 Rf	7.1 AU	4140.6 AU	43.84 %	unknown *
2	0.08 Rf	1.7 AU	0.12 Rf	147.3 AU	23.45 %	0.15 Rt	12.5 AU	2939.6 AU	31.12 %	unknown *
3	0.29 Rf		0.30 Rf	24.1 AU	3.83 %	0.32 Rf	5.7 AU	229.3 AU	2.43 %	unknown *
4	0.46 Rf	4.1 AU	0.48 Rf	41.3 AU	6.58 %	0.50 Rf	17.8 AU	830.3 AU	8.79 %	unknown *
5	A CARL CONTRACT	10.1 AU	0.62 Rf	19.5 AU	3.11 %	0.64 Rt	10.6 AU	355.5 AU	3.76 %	unknown *
6	0.65 Rf			12.0 AU	1.91 %	0.70 Rf	0.3 AU	314.3 AU	3.33 %	unknown *
7	0.79 Rf		0.81 Rf	12.9 AU	2.05 %	0.84 Rt	1.9 AU	314.6 AU	3.33 %	unknown *
8	0.84 Rf				2.56 %	0.88 Rf	11.3 AU	321.4 AU	3.40 %	unknown *





Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %	Assigned substance
1	-0.02 Rf	3.7 AU	0.00 Rf	211.0 AU	83.03 %	0.05 Rf	6.4 AU	2547.0 AU	80.00 %	unknown *
2	0.29 Rt	0.1 AU	0.30 Rf	23.5 AU	9.23 %	0.32 Rf	6.5 AU	208.1 AU	6.54 %	unknown *
3		5.7 AU		19.7 AU	7.74 %	0.50 Rf	13.4 AU	428.6 AU	13.46 %	unknown *

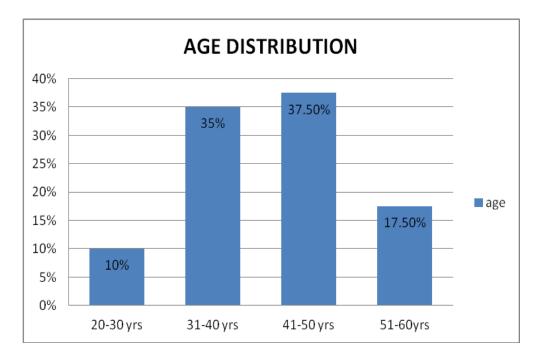
8-14la 18-

. iv -

### **OBSERVATION AND RESULTS**

### **1. AGE DISTRIBUTION**

AGE (YEARS)	NUMBER OF PATIENTS	PERCENTAGE %
20 - 30 yrs	4	10%
31 – 40 yrs	14	35%
41 – 50 yrs	15	37.5%
51 – 60 yrs	7	17.5%
Total	40	100%





### **Observation:**

10% (4) of the affected patients came under the age group between 20-30 years. 35 %(14) of the patients came under the age group between 31-40 years, 37.5 % (15)of them were between 41-50 years and 17.5 %(7) of them were between 51-60 years.

### 2. GENDER DISTRIBUTION

GENDER	NUMBER OF PATIENTS	PERCENTAGE %
Male	7	17.5%
Female	33	82.5%
Total	40	100%

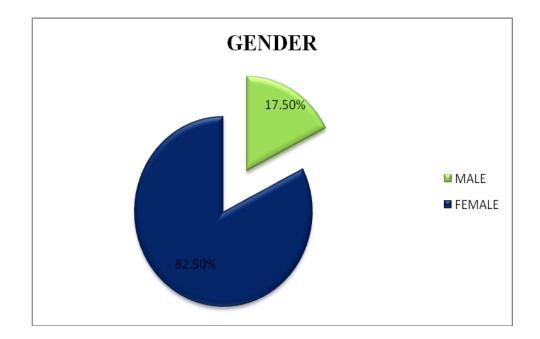


Fig.2. Gender Distribution

## **Observation:**

Among the 40 patients selected, the disease (R.A) was found to be higher in 33 females (82.5%) and lower in 7 males (17.5%).

### **3. MENOPAUSAL STATUS:**

MENSTURAL HISTORY	NUMBER OF PATIENTS	PERCENTAGE
NOT YET MENOPAUSE	23	69.69%
ATTAINED MENOPAUSE	8	24.24%
HYSTERECTOMY	2	6.06%
TOTAL	33	100%

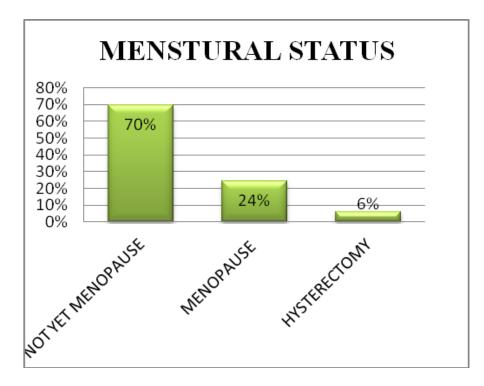


Fig.3. Menopausal status

### **Observation:**

In this study, Out of 33 females 8(24%) females attained menopause, 2(6%) females were in hysterectomy status.

## 4. GUNAM

GUNAM	NUMBER OF PATIENTS	PERCENTAGE(%)
Sathuvam	0	0%
Rasatham	38	95%
Thamasam	2	5%
Total	40	100%

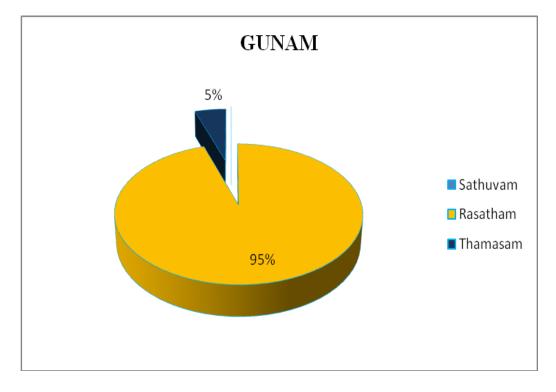


Fig. 4. Gunam

### **Observation:**

In Gunam, 38 cases (95%) had Rasatha gunam, 2 cases(5%) had Thamasa gunam.

### **5. BODY CONSTITUTION**

CONSTITUTION OF THE BODY	NUMBER OF PATIENTS	PERCENTAGE %
Vatha thegi	-	-
Pitha thegi	-	-
Kabam thegi	5	12.5%
Thontha thegi	35	87.5%

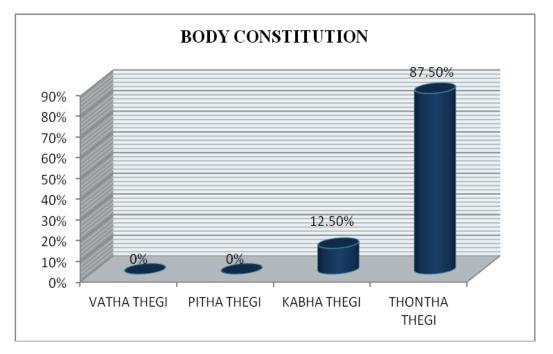


Fig. 5. Body constitution

### **Observation:**

Out of 40 cases,5 (12.5%)cases came under kabha thegi, 35 cases (87.5%) were came under Thontha Thegi.

# 6. EDUCATIONAL STATUS

EDUCATIONAL	NUMBER OF	PERCENTAGE
STATUS	PATIENTS	
Literate	24	60%
Ill literate	16	40%
TOTAL	40	100%

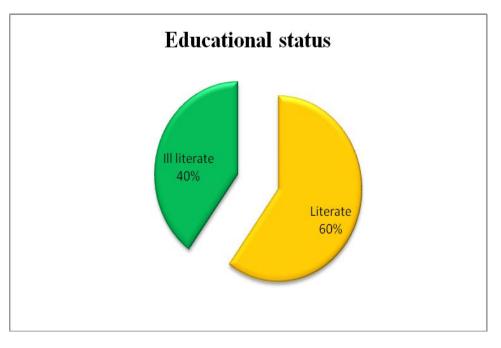


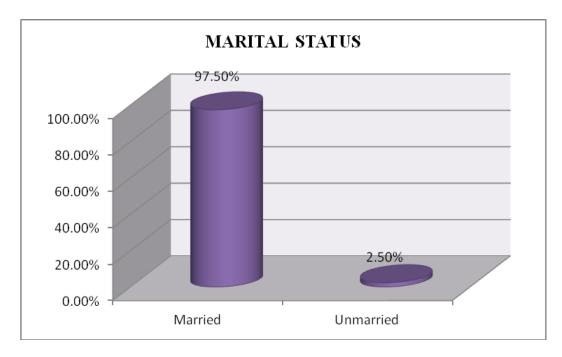
Fig.6. Educational Status

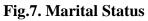
### **Observation:**

Among 40 cases 24 cases (60%) were literate and 16 cases (40%) were ill literate.

## 7. MARITAL STATUS

MARITAL STATUS	NUMBER OF PATIENTS	PERCENTAGE
Married	39	97.50%
Unmarried	1	2.50%
TOTAL	40	100%





### **Observation:**

Among 40 cases 39 (97.5%) got married and 1 case (2.5%) not married.

### 8. PARUVA KAALAM (SEASON)

SEASONS	Month and the year	Number of the patients	Percentage %
Kaarkaalam	17 <sup>th</sup> Aug-17 <sup>th</sup> Oct	-	-
Koothirkaalam	18 <sup>th</sup> Oct-15 <sup>th</sup> Dec	26	65%
Munpanikaalam	16 <sup>th</sup> Dec-12 <sup>th</sup> Feb	12	30%
Pinpanikaalam	13 <sup>th</sup> Feb-13 <sup>th</sup> Apr	2	5%
Ilavenil kaalam	14 <sup>th</sup> Apr-16 <sup>th</sup> June	-	-
Mudhuvenil kaalam	17 <sup>th</sup> June-16 <sup>th</sup> Aug	-	-
Total		40	100%

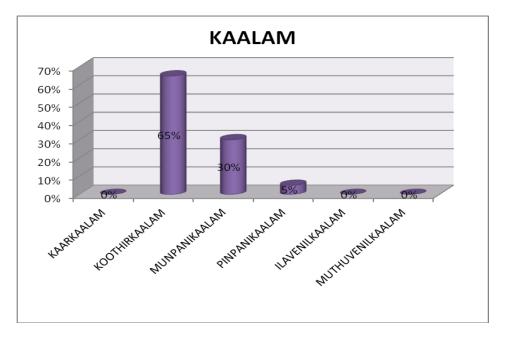


Fig.8. Paruva kaalam (Season)

#### **Observation:**

Out of 40 cases 26(65%) cases were included in Koothirkaalam , 12(30%) cases were included in Munpani kaalam and 2(5%) in Pinpani kalam.

### 9. THINAI

THINAI	Number of patients	Percentage %
Kurinji	2	5%
Mullai	-	-
Marutham	1	2.5%
Neithal	37	92.5%
Palai	-	-
Total	40	100%

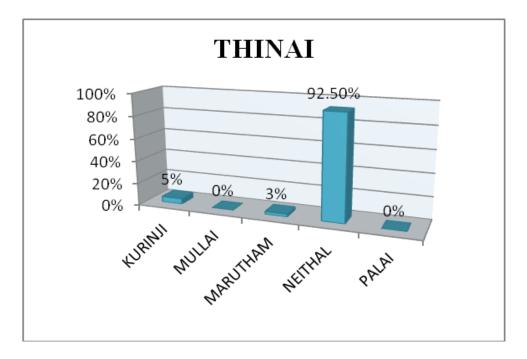


Fig.9. Thinai

# **Observation:**

Among the 40 cases, 37(92.5%) cases were from Neithal thinai and 2(5%) cases were from Kurinji thinai and 1(2.5%) case were from Marutham thinai.

# **10. DIET**

Diet	No of cases	Percentage %
Vegetarian	10	25%
Non vegetarian	30	75%
Total	40	100%

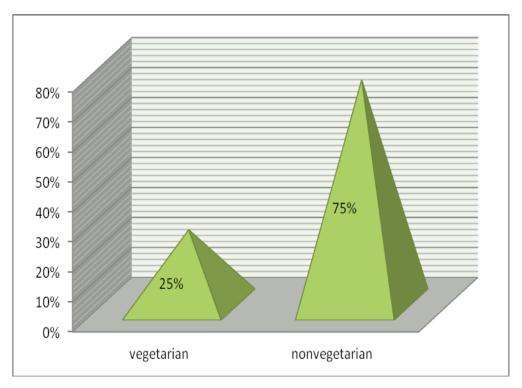


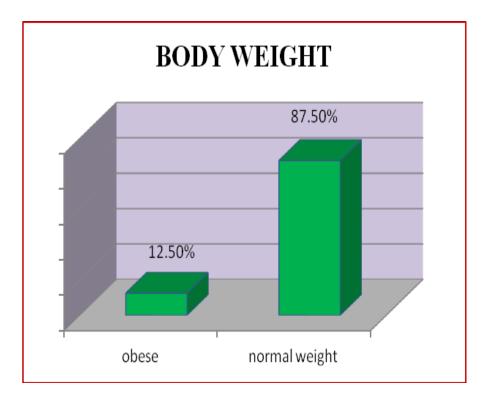
Fig.10. Diet

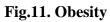
### **Observation:**

Out of 40 patients, 30 cases were Non vegetarian (75%) dieter and 10 cases were (25%) vegetarian dieter.

### **11. OBESITY**

OBESITY	NUMBER OF PATIENTS	PERCENTAGE
OBESE	5	12.5%
NORMAL WEIGHT	35	87.5%
TOTAL	40	100%





# **Observation:**

In this study 5 cases (12.5 %) were Obese and 35 cases (87.5 %) were belongs to normal weight.

#### **12. OCCUPATIONAL DISTRIBUTION**

OCCUPATION	NO. OF CASES	PERCENTAGE %
Home maker	30	75%
Farmer	1	2.5%
Driver	2	5%
Coolie	4	10%
Student	1	2.5%
Beautician	1	2.5%
Tailor	1	2.5%
Total	40	100%

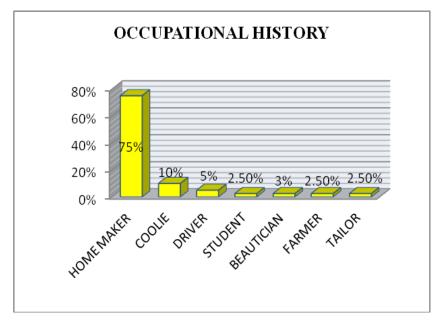


Fig.12. Occupational distribution

### **Observation:**

Among 40 cases, 30cases (75%) were home maker, 1case (2.5%) was Student,1 Case (2.5%) was Beautician, 4 Cases (10%) were cooli, 1 Case (2.5%) was Farmer, 2 cases (5%)were Driver, 1 case (2.5%) was tailer.

### **13. SOCIO-ECONOMIC STATUS**

Socio- economic status	No. of cases	Percentage %
Low Income Group	10	25%
Middle Income Group	29	72.5%
High Income Group	1	2.5%
Total	40	100%

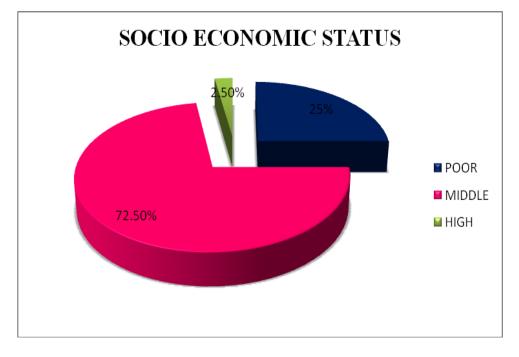


Fig.13. Socio-economic status

### **Observation**:

In my study the disease was found higher in the middle income group 29 cases (72.5%), Moderate in the low income group 25%(10 cases), Lower in the High income group 2.5% (1 case).

## **14. FAMILIAL HISTORY**

In this study family history of RA is present in one case (2.5%) in all 40 cases.

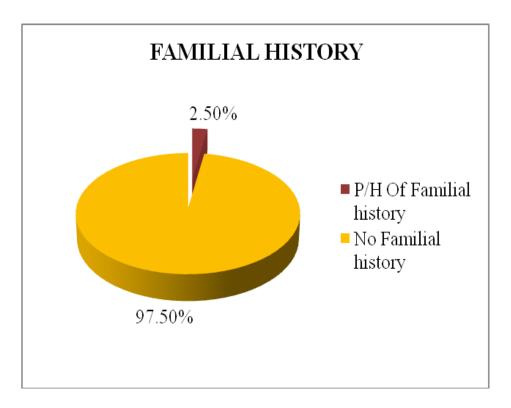
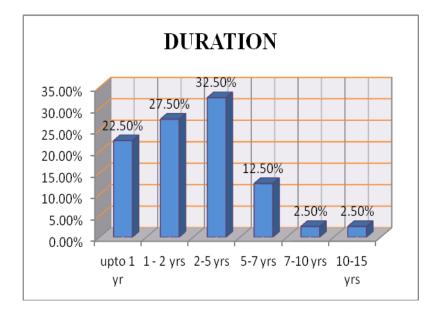
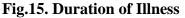


Fig.14. Family history

## **15. DURATION OF ILLNESS:**

DURATION OF ILLNESS	NUMBER OF CASES	PERCENTAGE %
Upto 1 yr	9	22.5%
1 year -2 years	11	27.5%
2 years-5 years	13	32.5%
5 years -7years	5	12.5%
7years-10 years	1	2.5%
10 years-15 years	1	2.5%
Total	40	100%



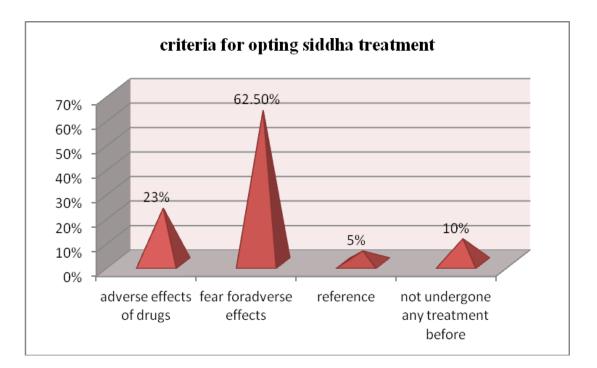


#### **Observation:**

In this study, about 9(22.5%) cases had symptoms upto 1 yr of duration,11(27.5%) cases had the sign and symptoms of RA 1 to 2 yrs of duration,13(32.5%) cases had 2-5 yrs of duration, 5(12.5%) cases had 5 to 7yrs of duration ,one (2.5%) case had 7-10 yrs and another one case (2.5%) had 10-15 yrs of duration.

#### 16. TREATMENTAL HISTORY OTHER THAN SIDDHA TREATMENT:

CRITERIA FOR OPTING SIDDHA TREATMENT	NO.OF CASES	PERCENTAGE
Adverse effects of drugs(like NSAIDS, Steroids)	9	22.5%
Fear for adverse effects	25	62.5%
Referred from rheumatologist	2	5%
Not undergone any treatment before	4	10%
Total	40	100%





### **Observation:**

Among 40 patients the reason for the patients to undergo Siddha treatment was more in 25 (62.5%) cases due to fear for adverse effects in other system of medicine. 9 cases (22.5%) due to Adverse effects of drugs, 2 cases (5%) were referred from Rheumatologist, and 4 cases (10%) were not undergo any treatment.

### **17. MODE OF ONSET**

Mode of onset	No of Cases	Percentage %
Gradual onset	30	75%
Sudden onset	10	25%
Total	40	100%

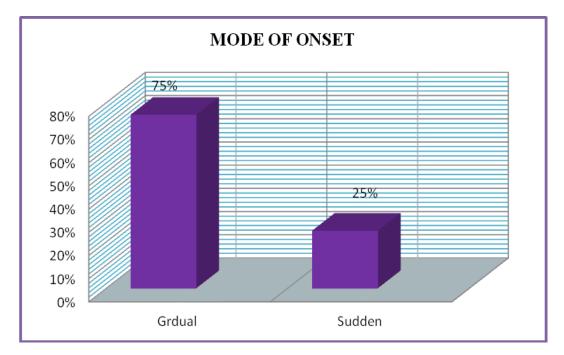


Fig. 17. Mode of Onset

### **Observation :**

In this study 30 cases(75%) had Gradual onset of illness, 10 cases(25%) had Sudden onset of the disease.

#### **18. INVOLVEMENT OF JOINTS:**

Name of the joint	BeforeTrt	After Trt	Before trt %	After trt %
Cervical joint	15	5	37.5%	12.5%
Elbow joint	35	10	87.5%	25%
Wrist joint	39	12	97.5%	30%
MCP joint	37	19	92.5%	47.5%
Knee joint	36	20	90%	50%
Ankle joint	35	24	87.5%	60%
PIP joint	40	25	100%	62.5%
Hip joint	10	5	25%	12.5%
Lumbosacral jt	14	8	35%	20%

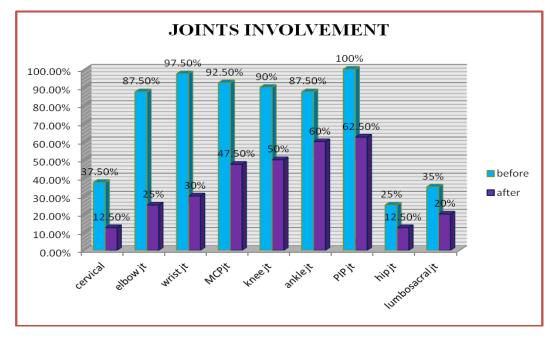


Fig.18. involvement of joints

#### **Observation:**

Cervical vertebrae were involved in 15cases (37.5%), elbow joint and ankle joint were involved in 35 cases(87.5%),39 cases (97.5%) in wrist joint, after treatment it was 12.5%,25%,60%,30% respectively. MCP joint was involved in 37 cases (92.5%), Knee joint in 36 cases 90% after treatment it was reduced 47.5% (19 cases) and 20 cases (50%). PIP joint were affected 40 cases (100%) before treatment, After treatment it was 62.5% (25 cases). Before treatment Lumbosacral joint was affected in 14 cases (35%) after treatment it was 20% (8 cases).

#### **19. NAADI**

NAADI	NUMBER OF PATIENTS	PERCENTAGE %
Vatha pitham	32	80%
Pitha vatham	3	7.5%
Pitha kabam	1	2.5%
Vatha kabam	2	5%
Kaba vatham	2	5%
Total	40	100%

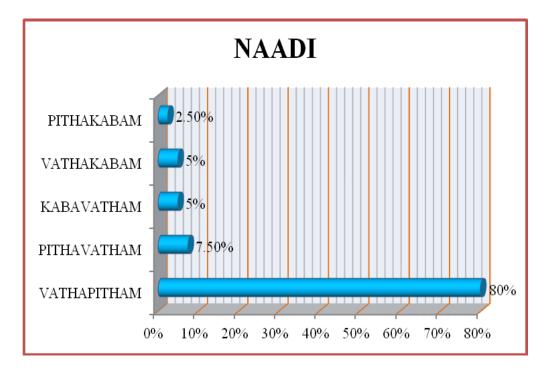


Fig. 19. Naadi

### **Observation :**

Among 40 cases, Vatha pitha naadi was found in 32 cases (80%), Pitha vatha naadi was found in 3 cases (7.5%), Pitha kaba naadi was found in 1 case (2.5%), Vaatha kaba naadi was found in 2 cases (5%) and kaba vatha naadi was found in 2 cases (5%).

#### **THREE HUMORS**

## **20. DISTURBANCES IN VALI**

VALI	NUMBER OF PATIENTS	PERCENTAGE %
Praanan	5	12.5%
Abaanan	37	92.5%
Udhaanan	-	-
Viyaanan	40	100%
Samaanan	40	100%
Naagan	1	2.5%
Koormam	-	-
Kirukaran	-	-
Devathatan	28	70%
Dhananjeyan	-	-

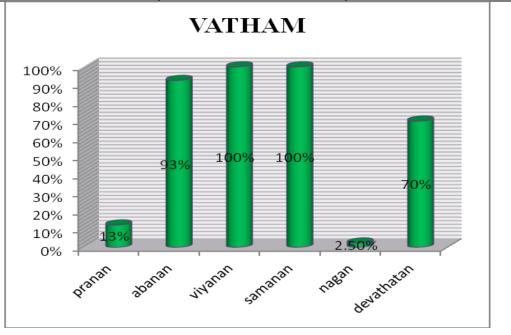


Fig.20. Disturbances in Vali

### **Observation:**

In Vatham, Viyaanan and Samanan were affected in all 40 cases (100%), pranan was affected in 5 cases(12.5%), Abanan was affected in 37 cases (92.5%) and Devathathan was affected in 28 cases (70%) and naagan was affected in 1 case(2.5%).

#### **21. DISTURBANCES IN AZHAL**

AZHAL	NUMBER OF PATIENTS	PERCENTAGE %
Analakam	31	77.5%
Ranjagam	27	67.5%
Saathagam	19	47.5%
Alosagam	-	-
Prasagam	-	-

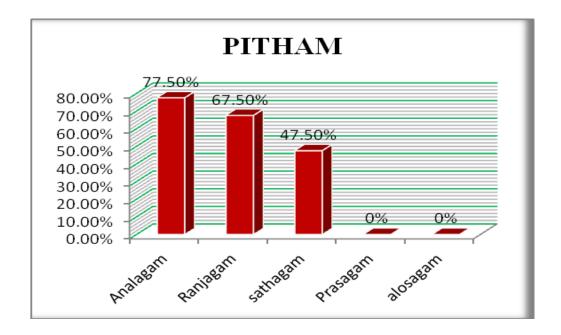


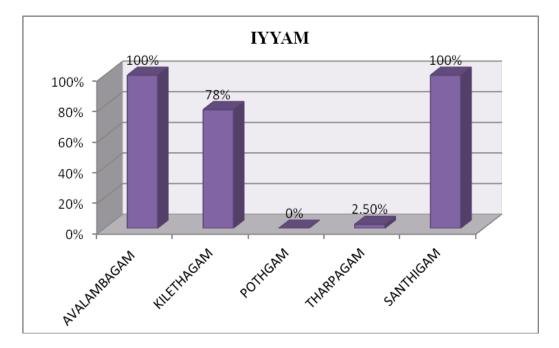
Fig. 21. Disturbances in Azhal

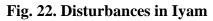
### **Observation:**

Among 40 cases, Analagam was affected in 31 cases (77.5%), Saathagam was affected in all 19 cases (47.5%), Ranjagam was affected in 27 cases(67.5%).

#### 22. DISTURBANCES IN IYAM

IYYAM	NUMBER OF PATIENTS	PERCENTAGE
AVALAMBAGAM	40	100%
KILETHAGAM	31	77.5%
POTHAGAM	0	0%
THARPAGAM	1	2.5%
SANTHIGAM	40	100%





### **Observation:**

Santhigam was affected in all the 40 cases(100%), Avalambagam affected in 40 cases (100%), kilethagam affected in 31 cases (78%)and tharpagam affected in 1 case(2.5%).

## 23. UDAL THAATHUKKAL

UDAL THAATHUKKAL	NUMBER OF PATIENTS	PERCENTAGE %
Saaram	40	100 %
Senneer	27	67.5%
Oon	40	100%
Kozhuppu	40	100%
Enbu	40	100%
Moolai	40	100%
Sukkilam / Suronitham	-	-

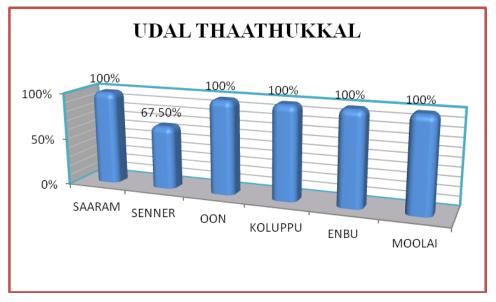


Fig.23. Udal Thaathukkal

### **Observation:**

In this study Saram, Oon, Kozhuppu, Enbu and moolai were affected in all 40 cases(100%) and Senneer was affected in 27(67.5%) cases only.

### 24. ENVAGAI THERVUGAL

ENVAGAI THERVUGAL	NUMBER OF CASES	PERCENTAGE %
Naadi (Thontha naadi)	40	100%
Sparisam	40	100%
Niram	-	-
Mozhi	-	-
Vizhi	27	67.5%
Naa	27	67.5%
Malam	37	92.50%
Moothiram	-	-

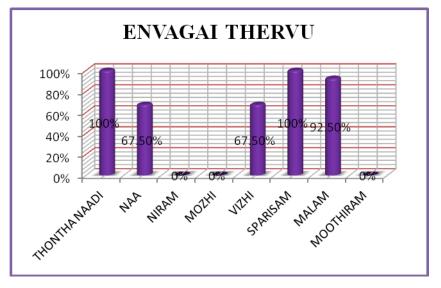


Fig.24. Envagai Thervugal

#### **Observation:**

In Envagai thervu, Thontha naadi in all 40 cases, Sparisam was affected in 40(100%) patients where as Vizhi was affected in 27 cases (67.5%), Naa was affected in 27 cases (67.5%) and Malam was affected in 37(92.5%) of patients.

#### 25. KOSANGAL:

NUMBER OF PATIENTS	PERCENTAGE
31	77.5%
5	12.5%
26	65%
40	100%
3	7.5%
	31 5 26 40

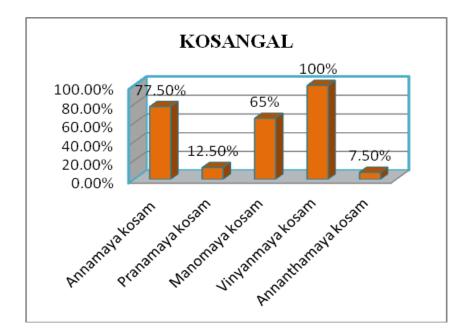


Fig.25. Kosangal

### Observation

In this study Annamaya kosam was affected in 31 cases(77.5%), Pranamaya kosam was affected in 5 cases(12.5%), Manomaya kosam was affected in 26 cases (65%), Vinyanamaya kosam was affected in 40 cases (100%) and Ananthamaya kosam affected in 3 cases (7.5%).

### **26. KANMENTHIRIYAM**

Kanmenthiriyam	No of cases	Percentage %
Kai	40	100%
Kaal	40	100%
Vai	-	-
Eruvai	37	92.5%
Karuvai	-	-

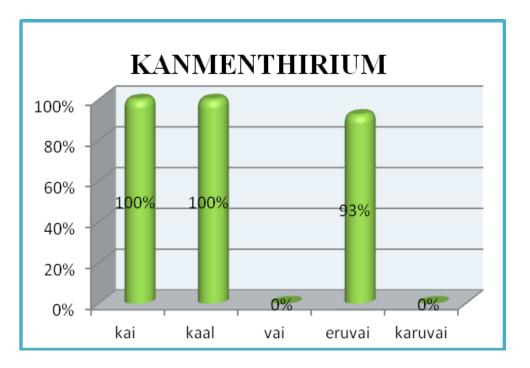


Fig 26. Kanmenthiriyam

### **Observation:**

In Kanmendrium Kai and Kaal were affected in 40(100%) cases, Eruvai was affected in 37 (92.5%) cases.

### **27. NEIKKURI**

SPREADING PATTERN	NUMBER OF PATIENTS	PERCENTAGE %
Aravena neendathu – Vatha neer	5	12.5%
Aazhi pol paraviyadhu – Pitha neer	-	0%
Muthothu nindrathu – Kaba neer	35	87.5%
Total	40	100%

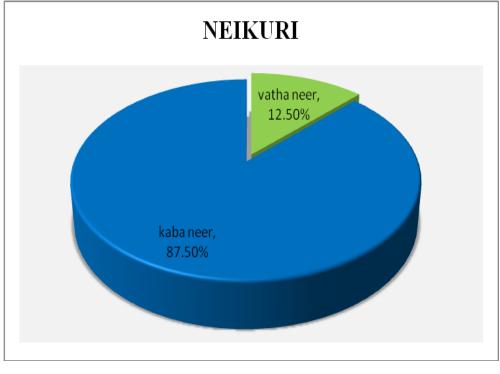


Fig.27. Neikkuri

# **Observation:**

Among 40 cases, Vatha neer was found in 5 cases (12.5%), and Kaba neer was found in 35 cases (87.5%).

## **28. DEFORMITIES:**

DEFORMITY	NO OF CASES	PERCENTAGE %
Button hole	7	17.5%
Swan neck	1	2.5%
Spindle shape deformity	11	27.5%
No deformity	21	52.5%

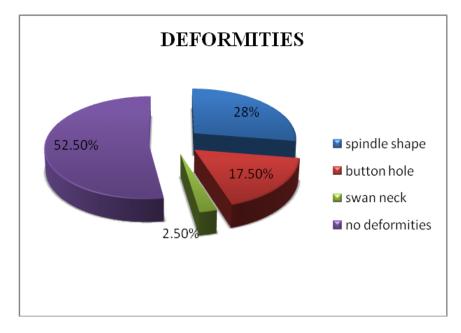


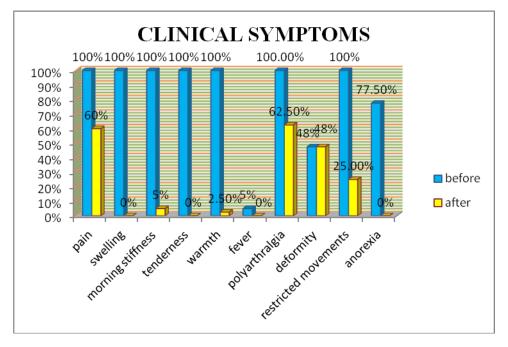
Fig.28. Deformities

# Observation

In this study, 11 cases (27.5%) had spindle shape deformity,7cases (17.5%) had buttonhole deformity and 1case (2.5%) had swan neck deformity. Remaining 21 cases (52.50%) had not any deformities.

#### **29. CLINICAL SYMPTOMS**

Clinical features	Before trt	After trt	Berfore trt%	After trt %
Pain	40	24	100%	60%
Swelling	40	0	100%	0%
Morning stiffness	40	2	100%	5%
Tenderness	40	0	100%	0%
Warmth	40	1	100%	2.5%
Fever	2	-	5%	0%
Poly arthralgia	40	25	100%	62.5%
Deformity	19	19	47.5%	47.5%
Restricted movements	40	10	100%	25%
Anorexia	31	-	77.5%	0%



**Fig.29.** Clinical Symptoms

## **Observation:**

In this study, all 40 cases (100%) had pain before treatment, after treatment it was reduced to 24 cases(60%). All 40 cases (100%) had swelling before treatment, after treatment no one had swelling. All 40 cases (100%) had morning stiffiness before treatment, after treatment it was reduced to 2 cases (5%). All 40 cases (100%) had tenderness before treatment, after treatment it was reduced to 0%. All 40 cases (100%) had warmth before

treatment, after treatment it was reduced to 1 case (2.5%). Before treatment 40 cases (100%) had polyarthralgia, after treatment it was reduced to 25 cases (62.5%). Deformitis remained the same before and after treatment in 19 cases (47.5%). Before treatment anorexia was in 31 cases (77.5%) after treatment no cases were reported with anorexia. Before treatment Fever was found in 2 cases (5%) which was releived after treatment. Before treatment 40 cases (77.5%) had restricted movements, after treatment it was reduced to 10 cases (25%).

# PRIMARY OUTCOME

# PAIN ASSESSMENT SCALE

# **30. REDUCTION OF PAIN**

Pain	Before T	reatment	After Treatment	
	No of patient	Percentage %	No of patient	Percentage %
Severe Pain	25	62.5%	0	0%
Moderate Pain	15	37.5%	1	2.5%
Mild Pain	0	0%	23	57.5%
No Pain	-	-	16	40%
Total	40	100%	40	100%

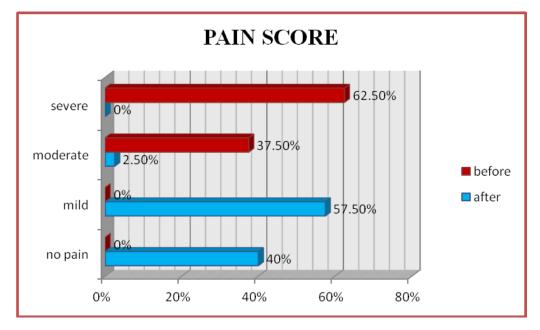


Fig.30. Reduction Of Pain

# **Observation:**

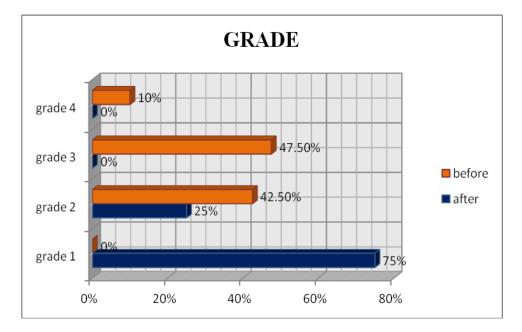
In this study, Before treatment 25 cases (62.5%) had Severe pain, 15 cases (37.50%) had Moderate pain. After treatment no one had Severe pain, one case(2.5%) had Moderate pain, 23 cases (57.5%) had Mild pain and 16 cases(40%) had No pain.

# **31. FUNCTIONAL ABILITY GRADATION**

Grade	No. of patients				
Graue	Before Treatment	%	After Treatment	%	
Grade IV	4	10%	0	0%	
Grade III	19	47.5%	0	0%	
Grade II	17	42.5%	10	25%	
Grade I	-	0%	30	75%	
Total	40	100%	40	100%	

Grade I - Fit fo	or all activities
------------------	-------------------

- Grade II Mild restriction
- Grade III Moderate restriction
- Grade IV Confined to chair or bed ridden





# **Observation:**

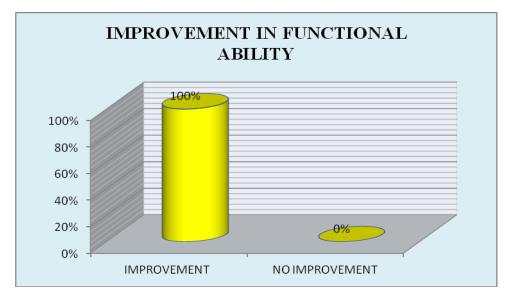
Among 40 cases, Before treatment 4 (10%)cases came under grade IV and 19 (47.5%) cases came under Grade III, 17(42.5%) cases in Grade II. after treatment no one came under Grade IV and III ,10(25%) cases came under Grade II and 30 cases (75%) came under Grade I.

### **32. IMPROVEMENT IN FUNCTIONAL ABILITY ASSESSMENT PER PATIENT:**

As per Cross tabulation 31

	AFTER TREATMENT FUNCTIONAL ABILITY					
		Ι	II	III	IV	TOTAL
BT	II	17	0	0	0	17
	III	12	7	0	0	19
	IV	1	3	0	0	4
TO	ΓAL	30	10	0	0	40

#### Before treatment functional ability –After treatment functional ability





# **Observation:**

Before treatment 4 cases (10%) came under grade IV after treatment 1 case (2.5%) under grade I and 3 cases (7.5%) under Grade II. Before treatment 19 cases (47.5%) came under Grade III after treatment 12 cases (30%) came under grade I and 7 cases (17.5%) came under grade II, Before treatment 17(42.5%) cases in Grade II after treatment all 17 (42.5%) cases came under Grade I.

In this study, 100% cases showed improvement in functional ability.

# SECONDARY OUTCOME

# LAB PARAMETERS

# **33. RA FACTOR**

Before	Number of	Percentage	After	Number	Percentage
treatment	patients		treatment	of cases	
POSITIVE	27	67.5%	POSITIVE	18	45%

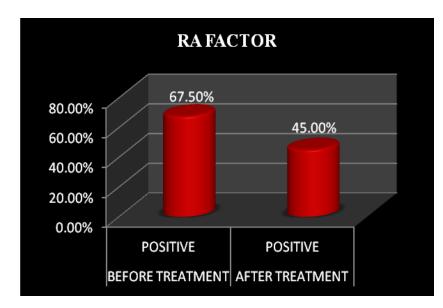


Fig.33. RA Factor

# **Observation:**

Among 27 cases (67.5%) who are positive at commencement of the treatment 9 (33.3%) were screened negative and 18 cases (45%) remained positive for RA factor after the treatment.

## **34. C-REACTIVE PROTEIN**

Before	Number of	Percentage	After	Number	Percentage
treatment	patients		treatment	of cases	
POSITIVE	25	62.5%	POSITIVE	19	47.5%

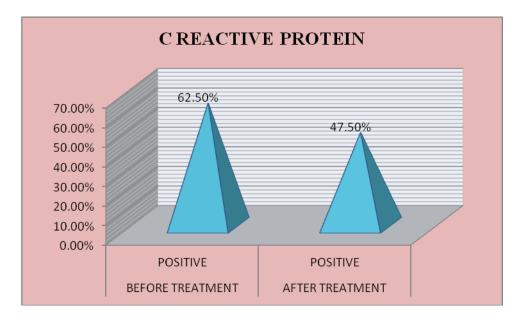


Fig.34. C - reactive protein

# **Observation:**

Among 25 cases (62.5%) who are positive at commencement of the treatment 6(24%) were screened negative and 19 cases (47.5%) remained positive for C reactive protein after the treatment.

# **35. ASO TITRE**

Before	Number of	Percentage	After	Number	Percentage
treatment	patients		treatment	of cases	
POSITIVE	10	25%	POSITIVE	8	20%

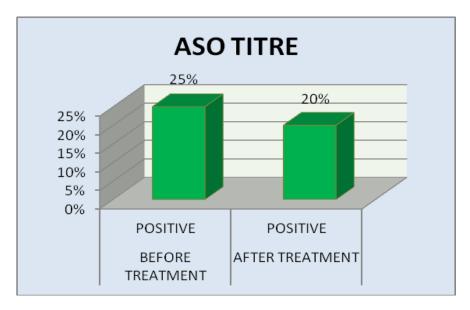


Fig.35. ASO Titre

# **Observation:**

Among 10 cases who are positive at commencement of the treatment 2(20%) cases were screened negative and 8 (20%) cases remained positive for Aso titre after the treatment.

# STATISTICAL ANALYSIS

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean  $\pm$  Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment. In my study statistical analysis was done for pain score and all Blood investigations to find the significance of the treatment statistically.

#### **Paired Samples Statistics**

#### A) PAIN SCORE

PAIN SCORE	$\mathbf{MEAN} \pm \mathbf{SD}$	t VALUE	p VALUE
Before treatment	7 ± 1.22	28.50	P < 0.001
After treatment	1.3±1.24		

The mean $\pm$  standard deviation of pain score before and after treatment were  $7 \pm 1.22$ and  $1.3\pm1.24$  respectively which is **statistically significant** (p<0.001) The analysis revels that significant reduction of pain with the trial drug i.e. there is **81.4%** reduction in pain compared to start of the treatment.

ESR (1/2 AN HOUR)	$\mathbf{MEAN} \pm \mathbf{SD}$	t VALUE	p VALUE
Before treatment	32.02± 19.75	6.09	P < 0.001
After treatment	16.1 ±10.91		

## **B.) ERTHROCYTE SEDIMENTATION RATE (ESR)**

ESR (1 HOUR)	$\mathbf{MEAN} \pm \mathbf{SD}$	t VALUE	p VALUE
Before treatment	57.97± 32.54	6.84	P < 0.001
After treatment	27.57 ±19.52		

The mean  $\pm$  standard deviation before treatment is  $32.02 \pm 19.75$  and after treatment is  $16.1 \pm 10.91$  for  $\frac{1}{2}$  hr. The analysis revels that there is 49.7% reduction in ESR  $\frac{1}{2}$  hr compared to start of the treatment.

The mean  $\pm$  standard deviation before treatment is 57.97 $\pm$  32.54 and after treatment is 27.57  $\pm$ 19.52 for 1 hr. The analysis revels that there is 52.44% reduction in ESR 1 hr compared to start of the treatment.

The statistical analysis reveals that there has been a **significant reduction in ESR** value after treatment indicating the control over the inflammatory process of the disease.

# HAEMOGLOBIN

HAEMOGLOBIN	MEAN ± SD	t VALUE	p VALUE
Before treatment	11.44 ± 2.57	-1.2252	P > 0.2279
After treatment	11.78±1.83		

The mean  $\pm$  standard deviation before treatment is **11.44** $\pm$  **2.57** and after treatment is **11.78** $\pm$ **1.83**. The analysis revels that among 40 cases, there was no significant increase after the treatment statistically.

SL NO	OP	AGE	SEX				
110	NO/IP NO	nol	<b>BLA</b>		SEROLO	GY	
				RA before	RA after	ASO titre before	ASO titre after
1	109544	25	F	+ ve	- ve	- ve	- ve
2	159413	41	F	+ ve	+ ve	- ve	- ve
3	J35977	54	F	+ ve	+ ve	- ve	- ve
4	H94125	48	F	+ ve	+ ve	- ve	- ve
5	J22144	40	F	+ ve	- ve	+ ve	+ ve
6	J70445	48	F	+ ve	- ve	+ ve	+ ve
7	0075-18 (IP)	46	F	+ ve	- ve	- ve	- ve
8	J73469	40	F	- ve	- ve	- ve	- ve
9	H77668	40	М	+ ve	- ve	+ ve	+ ve
10	G15638	22	M	- ve	- ve	- ve	- ve
11	I10061	47	M	+ ve	+ ve	- ve	- ve
12	J73797	36	M	- ve	- ve	- ve	- ve
13							
14	J65069	32	M	- ve	- ve	- ve	- ve
15	J74063	55	F	+ ve	+ ve	- ve	- ve
16	I32409	50	F	- ve	- ve	- ve	- ve
17	J65774	30	F	+ ve	+ ve	+ ve	+ ve
18	J44905	44	F	- ve	- ve	- ve	- ve
19	J64112	47	F	+ ve	+ ve	+ ve	+ ve
20	I14459	32	F	- ve	- ve	+ ve	- ve
20	I97794	47	М	+ ve	+ ve	- ve	- ve

SL NO	OP NO	AGE	SEX				
					SEROLOG	Ϋ́Υ	
				RA before	RA after	ASO titre before	ASO titre after
21	F91016	40	F	- ve	- ve	- ve	- ve
22	J67779	50	М	- ve	- ve	- ve	- ve
23	J69753	42	F	+ ve	+ ve	+ ve	+ ve
24	H91904	36	F	- ve	- ve	- ve	- ve
25	173928	33	F	+ ve	- ve	+ ve	+ ve
26	H15822	50	F	+ ve	- ve	- ve	- ve
27	G17963	48	F	+ ve	+ ve	- ve	- ve
28	J77255	38	F	+ ve	+ ve	+ ve	- ve
29	J57078	52	F	- ve	- ve	- ve	- ve
30	J75796	58	F	+ ve	+ ve	- ve	- ve
31	J73061	39	F	+ ve	+ ve	- ve	- ve
32	J64099	49	F	- ve	- ve	- ve	- ve
33	J83067	56	F	+ ve	+ ve	- ve	- ve
34	I48032	36	F	+ ve	+ ve	- ve	- ve
35	H62467	38	F	+ ve	- ve	- ve	- ve
36	J10306	55	F	+ ve	+ ve	- ve	- ve
37	I85405	58	F	- ve	- ve	- ve	- ve
38	H88015	39	F	+ ve	- ve	- ve	- ve
39	K04937	27	F	+ ve	+ ve	+ ve	+ ve
40	D0092	44	F	+ ve	+ ve	- ve	- ve

S.NO	OP NO/IP	AGE	SEX	SEROLOGY	
	NO			C-Reactive protein before	C-Reactive protein after
1	109544	25	F	+ ve	+ 1/0
2	109544			+ VE	+ ve
3	I59413	41	F	- ve	- ve
5	J35977	54	F	+ ve	+ ve
4	H94125	48	F	+ ve	+ ve
5	J22144	40	F	+ ve	+ ve
6	J70445	48	F	- ve	- ve
7	0075-18 (IP)	46	F	+ ve	+ ve
8	J73469	40	F	+ ve	+ ve
9	H77668	40	М	+ ve	+ ve
10	G15638	22	М	- ve	- ve
11	I10061	47	М	+ ve	+ ve
12	J73797	36	М	- ve	- ve
13	J65069	32	М	+ ve	- ve
14	J74063	55	F	+ ve	+ ve
15	132409	50	F	- ve	- ve
16	J65774	30	F	+ ve	- ve
17	J44905	44	F	- ve	- ve
18	J64112	47	F	+ ve	+ ve
19	I14459	32	F	+ ve	+ ve
20	I97794	47	М	+ ve	+ ve

6 NO		105	65%	SERO	LOGY
S. NO	OP NO	AGE	SEX	CRP before	CRP after
21				CRP Defore	CKP alter
21	F91016	40	F	- ve	- ve
22					
	J67779	50	M	+ ve	- ve
23			F		
24	J69753	42	-	+ ve	+ ve
24	H91904	36	F	+ ve	+ ve
25	191904	50	F	+ ve	+ ve
25	173928	33	•	+ ve	+ ve
26			F		
_	H15822	50		+ ve	+ ve
27			F		
	G17963	48		- ve	- ve
28			F		
	J77255	38		- ve	- ve
29			F		
	J57078	52		+ ve	- ve
30			F		
	J75796	58		- ve	- ve
31	172064	20	F		
22	J73061	39		- ve	- ve
32	J64099	49	F		
33	104099	49	F	+ ve	+ ve
	J83067	56	•	+ ve	240
34	102007	50	F	+ VE	- ve
	148032	36		- ve	- ve
35			F		
	H62467	38		- ve	- ve
36			F		
	J10306	55		+ ve	+ ve
37			F		
	185405	58		- ve	- ve
38			F		
	H88015	39		+ ve	+ ve
39	K0 4007	~~	F		
40	K04937	27	-	+ ve	- ve
40	D0003		F		
	D0092	44		- ve	- ve

SL NO	OP NO/IP NO		Haemoglobin (gm/dl)		BC count /µL)	Total RBC count (million/ μL)		
		Before	After	Before	After	Before	After	
1	109544	10.4	10.3	6800	7600	4.2	4.2	
2	159413	6.8	8	3300	3900	3.5	3.9	
3	J35977	8.7	8.8	7500	8900	3.7	3.8	
4	H94125	11.6	11.5	9300	8500	4.1	4	
5	J22144	12.1	12.1	6600	6200	3.9	3.9	
6	J70445	12.2	12.3	6200	5400	4.3	4.2	
7	0075-18(IP)	7	6.6	6900	6400	3.7	3.6	
8	J73469	10.9	11.1	7800	7800	4.5	4.6	
9	H77668	14.4	13.5	8000	9500	5.7	5.4	
10	G15638	15.2	14.6	7200	8000	5.1	4.8	
11	I10061	13.6	13.4	8800	9200	4.6	4.6	
12	J73797	15	15.2	7100	7200	5	5.1	
13	J65069	15	15.1	7300	7200	5.2	5.2	
14	J74063	10.7	10.9	14300	11200	4.4	4.4	
15	132409	11.2	11.1	6000	6900	4.7	4.6	
16	J65774	10.4	11.2	6700	6900	4.6	4.6	
17	J44905	13.2	13.2	6800	6500	4.6	4.7	
18	J64112	12.3	12.1	8900	10900	4.7	5.1	
19	I14459	11.2	11.6	4900	5100	4	4.1	
20	197794	14.7	14.9	8500	7700	5.1	5.2	
21	F91016	10.4	11.4	8700	9000	3.9	4	
22	J67779	12.9	13	6900	6000	4.6	4.8	
23	J69753	11.6	11.8	6200	7100	4.8	4.8	
24	H91904	11.5	11.6	11800	11400	4.2	4.8	
25	173928	8.3	8.5	4500	4480	3.5	3.5	
26	H15822	12.7	12.6	5700	5710	4.3	4.2	
27	G17963	11.5	11.5	10800	10600	4.2	4.2	
28	J77255	9.7	9.8	9000	9400	4.5	4.5	
29	J57078	11.9	11.8	3400	4200	4.3	4.3	
30	J75796	13.3	13	6800	7500	4.3	4.3	
31	J73061	12.1	12.1	6700	5800	4.7	4.7	
32	J64099	12.2	11.9	6800	9000	4.4	4.3	
33	J83067	9.3	10.1	7400	7500	4	4.1	
34	148032	14	14.1	7100	7200	4.7	4.7	
35	H62467	10.9	11	9400	9500	4	4	
36	J10306	12	12.1	6900	7000	4.2	4.2	
37	185405	11.4	11.1	6800	5400	4.2	4.1	
38	H88015	12	12.1	10400	9600	4.5	4.5	
39	K04937	12.1	12.1	7530	7600	4.2	4.2	
40	D0092	1.3	12.2	6300	7400	4.2	4.2	

SL	OP NO/IP			Differential	count		
NO	NO	Polymorphs before (%)	Polymorphs after (%)	Lymphocyt es before (%)	Lymphocytes after (%)	Monocytes before (%)	Monocyte s after (%)
1	109544	56	64	39	31	3	2
2	159413	58	60	40	36	0	0
3	J35977	58	69	37	28	2	0
4	H94125	71	71	26	27	0	0
5	J22144	60	45	39	48	0	3
6	J70445	53	50	42	45	2	2
7	0075-18(IP)	73	67	24	28	0	2
8	J73469	66	64	31	34	1	0
9	H77668	68	78	29	20	1	0
10	G15638	69	74	28	23	0	0
11	110061	60	62	31	25	0	4
12	J73797	70	69	27	28	0	1
13	J65069	60	61	37	38	1	0
14	J74063	72	68	26	29	0	1
15	132409	46	64	49	30	1	2
16	J65774	55	58	42	41	1	0
17	J44905	53	48	44	50	1	0
18	J64112	66.3	74	23.8	24	4.3	0
19	I14459	50	54	43	43	2	1
20	197794	58	63	38	35	0	0
21	F91016	68	71	24	26	3	1
22	J67779	75	72	23	27	0	0
23	J69753	60	61	36	36	0	1
24	H91904	65	63	33	35	0	0
25	173928	59	60	38	38	1	1
26	H15822	60	50	33	30	0	4
27	G17963	64	63	34	34	0	1
28	J77255	61	65	31	32	2	1
29	J57078	62	63	33	34	2	2
30	J75796	65	64	32	33	0	0
31	J73061	65	60	30	37	1	0
32	J64099	52	43	45	54	1	0
33	J83067	62	63	36	35	0	1
34	148032	67	66	30	29	0	2
35	H62467	76	77	19	20	2	1
36	J10306	64	65	34	34	0	1
37	185405	70	65	27	30	1	2
38	H88015	77	76	21	20	0	2
39	К04937	63	66	32	33	2	1
40	D0092	67	68	30	30	1	1

SL NO	OP NO/IP NO		Different	ial count		Platalat aa	unt lkhs/µL
		Eosinophils before (%)	Eosinophils after (%)	Basophils before(%)	Basophils after(%)	Before	After
1	109544	2	3	0	0	4.7	4.1
2	159413	2	4	0	0	5	5
3	J35977	3	3	0	0	6.1	5.8
4	H94125	3	2	0	0	3	3.1
5	J22144	1	4	0	0	2.9	2.9
6	J70445	3	3	0	0	2.5	2.5
7	007518(IP)	3	3	0	0	5.2	5.4
8	J73469	2	2	0	0	4	4
9	H77668	2	2	0	0	2.7	2.7
10	G15638	3	3	0	0	2	2.1
11	I10061	9	9	0	0	3	3
12	J73797	3	2	0	0	2	2.1
13	J65069	2	1	0	0	1.9	1.9
14	J74063	2	2	0	0	5.5	5.5
15	132409	4	4	0	0	3.4	3.4
16	J65774	2	1	0	0	2.5	2.6
17	J44905	2	2	0	0	2.5	2.3
18	J64112	5.4	2	0.2	0	2.4	2.5
19	I14459	4	2	1	0	3.1	3.1
20	197794	4	2	0	0	3.6	3.5
21	F91016	5	2	0	0	1.5	1.5
22	J67779	2	1	0	0	2	2
23	J69753	4	2	0	0	2.5	2.5
24	H91904	2	2	0	0	3.3	3.3
25	173928	2	1	0	0	2.3	2.3
26	H15822	7	6	0	0	2.4	2.3
27	G17963	2	2	0	0	3.3	3.3
28	J77255	6	2	0	0	4	4
29	J57078	3	1	0	0	2.3	2.4
30	J75796	3	3	0	0	2.2	2.3
31	J73061	4	3	0	0	3.4	3.2
32	J64099	2	3	0	0	4	3.6
33	J83067	2	1	0	0	1.8	1.8
34	148032	3	3	0	0	2.9	2.9
35	H62467	3	2	0	0	3.4	3.4
36	J10306	2	1	0	0	2.9	2.9
37	185405	2	3	0	0	2.8	2.1
38	H88015	2	2	0	0	3.5	3.5
39	K04937	3	0	0	0	2.1	2.1
40	D0092	2	1	0	0	2.4	2.4

SL NO	OP NO/IP NO	Erythrocytese n rate ½ hr (n		Erythrocytese rate 1 h		PCV	(%)
		before	after	before	after	before	After
1	109544	42	12	24	20	31.8	32
2	159413	40	30	80	62	23.6	26.8
3	J35977	40	34	80	70	29.5	29.3
4	H94125	12	26	24	52	33.8	38
5	J22144	44	14	90	38	34.7	34.6
6	J70445	40	18	80	20	35.7	35.8
7	0075-18(IP)	44	4	90	10	25.8	24.2
8	J73469	10	10	20	20	35.4	35.5
9	H77668	14	6	30	14	42.5	43.2
10	G15638	14	4	30	8	44.3	42.7
11	110061	20	10	42	18	38.9	38.8
12	J73797	40	14	82	30	44	44.3
13	J65069	10	4	20	10	42.7	41
14	J74063	54	24	110	38	34.7	33.8
15	132409	10	20	20	40	35.4	34.6
16	J65774	15	10	32	12	40.1	40
17	J44905	14	10	30	22	40.2	39.4
18	J64112	38	17	54	12	36.9	37
19	114459	80	24	100	41	32.9	33.4
20	197794	24	12	50	26	44.4	44.6
21	F91016	40	19	68	24	37.5	37
22	J67779	20	2	40	4	37.9	38.4
23	J69753	64	20	130	40	36	37.2
24	H91904	16	12	32	20	35	34.6
25	173928	40	18	80	24	26.3	28
26	H15822	20	19	42	18	36.9	36.7
27	G17963	15	12	32	20	35	36.1
28	J77255	10	7	20	10	32.5	31.5
29	J57078	64	20	130	40	35.3	35.2
30	J75796	18	8	28	18	39.6	38.1
31	J73061	12	10	24	12	36.9	37
32	J64099	46	60	92	100	37.6	36
33	J83067	30	10	62	14	36.1	36
34	148032	8	10	16	18	39.7	38.5
35	H62467	42	12	54	20	36.8	36.4
36	J10306	40	21	82	40	35	36.1
37	185405	90	40	100	60	35	33.4
38	H88015	30	11	62	18	36.6	35.5
39	K04937	37	20	89	24	40	39
40	D0092	34	10	48	16	35.2	35

SL NO	OP NO/IP	MCV	(% ft)	MCH	[ (pg)	MCHC	(gm/dL)
	NO	before	after	before	after	before	after
1	109544	75.4	75.8	24.6	24.4	32.7	32.2
2	159413	66.5	67.7	19.2	20.2	28.8	29.9
3	J35977	78	76.7	23	23	29.5	30
4	H94125	81.6	80.9	28	28.2	34.3	34.8
5	J22144	88.1	88.3	30.9	30.9	34.9	38.9
6	J70445	82.3	81.4	28.1	28	34.2	34.2
7	007518(IP)	68.6	66.1	18.6	18	27.1	27.3
8	J73469	77.5	77	23.9	24.1	30.8	31.3
9	H77668	74.2	73.9	25.1	24.8	33.9	33.6
10	G15638	86.4	88.2	29.6	30.2	34.3	34.2
11	I10061	84.4	84.3	29.5	29	25	34.5
12	J73797	84.4	86	29	29.6	34	34.3
13	J65069	80.9	81.2	28.4	30	35.1	34
14	J74063	77.5	79.1	23.9	26.4	30.8	31.4
15	132409	74.4	74.1	23.5	23.8	31.6	32.1
16	J65774	84.9	85.4	29.2	28.4	32.8	33.2
17	J44905	85.9	83.1	28.2	27.8	32.8	33.5
18	J64112	78.3	79	26.1	27	33.3	34
19	114459	82	82.5	27.9	27.5	34	34.2
20	197794	85.5	85	28.3	28.4	33.1	33.4
21	F91016	85	84.5	32.4	32	32.5	32.5
22	J67779	80.8	79.2	27.5	26.8	34	33.9
23	J69753	74.7	75	24.1	24.4	32.2	31.8
24	H91904	82.5	82.4	27	27.6	32.9	33.5
25	173928	73.3	75.3	23.1	23	31.6	31
26	H15822	85.6	85.6	29.5	29.4	34.4	34.4
27	G17963	82.5	82	27	27.2	33	33.1
28	J77255	71.7	70.4	21.4	20.5	29.8	29.9
29	J57078	81.5	80.4	27.5	28	33.7	34.2
30	J75796	90.4	87.8	30.4	30	33.6	34.1
31	J73061	77.7	77.9	25.7	25.5	32.8	32.7
32	J64099	85.1	83.5	27.6	27.6	32.4	33.1
33	J83067	80.1	80.4	26.4	24.4	32.4	32.5
34	148032	84.5	84	29.8	29.5	35.3	35
35	H62467	84.2	84	27.2	27.1	83.4	82.8
36	J10306	81.6	82.6	28	28.1	34.3	34.5
37	185405	81.6	80.1	26.6	26.6	32.6	33.2
38	H88015	80.3	79.2	26.3	26.2	32.8	32.4
39	K04937	82.2	82.4	30.4	31.2	36.2	36
40	D0092	79.5	84.5	30.5	29	34.8	32.4

SL	OP NO/IP		B	lood sugar		Blood	Blood
NO	NO	Fasti	ng (mg/dl)	Post pra	andial(mg/dl)	Urea	Urea
		before	after	before	After	before(mg/dl)	after(mg/dl)
1	109544	83	82	119	92	11	14
2	159413	86	83	109	112	11	9
3	J35977	91	103	108	130	22	11
4	H94125	85	90	102	104	35	37
5	J22144	86	95	137	115	24	17
6	J70445	96	90	87	100	28	27
7	007518(IP)	91	89	119	82	11	14
8	J73469	90	92	110	114	16	16
9	H77668	80	88	95	99	19	16
10	G15638	86	90	89	89	10	7
11	I10061	85	87	93	113	14	15
12	J73797	90	86	110	89	10	14
13	J65069	77	90	100	110	24	28
14	J74063	119	120	140	138	18	20
15	132409	94	96	99	84	23	13
16	J65774	80	95	110	115	15	18
17	J44905	88	90	95	139	15	17
18	J64112	80	91	100	119	18	15
19	I14459	92	89	110	120	14	16
20	197794	85	87	101	106	15	13
21	F91016	70	85	100	110	17	18
22	J67779	126	123	145	210	18	20
23	J69753	81	90	130	120	12	16
24	H91904	88	90	105	120	17	15
25	173928	76	90	110	120	18	20
26	H15822	90	92	71	100	15	15
27	G17963	88	100	105	120	18	20
28	J77255	91	106	106	120	18	20
29	J57078	88	90	127	130	13	16
30	J75796	108	109	96	116	16	14
31	J73061	90	96	110	120	18	19
32	J64099	86	85	119	102	20	22
33	J83067	82	90	102	110	15	20
34	148032	83	90	112	130	13	18
35	H62467	90	94	130	135	12	14
36	J10306	102	110	128	130	17	18
37	185405	102	101	91	118	14	11
38	H88015	84	90	147	138	9	10
39	K04937	90	102	110	130	41	35
40	D0092	98	180	118	120	19	20

SL	OP NO/IP Liver function test (mg/dl)						
NO	NO	T.bilirubin	T.bilirubin	D.bilirubin	D.bilirubin	I.bilirubin	I.bilirubin
	<u> </u>	before	after	before	after	before	after
1	109544	0.3	0.2	0.1	0.1	0.2	0.3
2	159413	0.2	0.3	0.1	0.1	0.1	0.2
3	J35977	0.3	0.3	0.2	0.1	0.1	0.3
4	H94125	0.2	0.3	0.1	0.1	0.1	0.2
5	J22144	0.6	0.2	0.3	0.1	0.3	0.6
6	J70445	0.6	0.4	0.3	0.3	0.3	0.6
7	007518(IP)	0.3	0.2	0.1	0.1	0.2	0.3
8	J73469	0.3	0.3	0.1	0.1	0.2	0.3
9	H77668	0.6	0.5	0.2	0.2	0.4	0.6
10	G15638	0.5	0.5	0.3	0.3	0.3	0.5
11	I10061	0.5	0.3	0.2	0.2	0.3	0.5
12	J73797	0.5	0.4	0.3	0.1	0.3	0.5
13	J65069	0.9	0.8	0.3	0.2	0.5	0.9
14	J74063	0.3	0.3	0.1	0.2	0.2	0.3
15	132409	0.3	0.3	0.1	0.1	0.2	0.3
16	J65774	0.5	0.4	0.2	0.2	0.2	0.5
17	J44905	0.5	0.5	0.2	0.2	0.3	0.5
18	J64112	0.4	0.6	0.1	0.2	0.2	0.4
19	I14459	0.3	0.2	0.1	0.1	0.2	0.3
20	197794	0.4	0.4	0.1	0.1	0.3	0.4
21	F91016	0.3	0.2	0.2	0.2	0.1	0.3
22	J67779	0.5	0.6	0.2	0.2	0.2	0.5
23	J69753	0.3	0.3	0.1	0.2	0.2	0.3
24	H91904	0.3	0.3	0.2	0.1	0.1	0.3
25	173928	0.2	0.9	0.1	0.1	0.1	0.2
26	H15822	0.4	0.3	0.2	0.2	0.2	0.4
27	G17963	0.2	0.3	0.2	0.2	0.1	0.2
28	J77255	0.2	0.3	0.1	0.2	0.1	0.2
29	J57078	0.3	0.2	0.2	0.1	0.1	0.3
30	J75796	0.5	0.5	0.2	0.2	0.3	0.5
31	J73061	0.3	0.2	0.1	0.1	0.2	0.3
32	J64099	0.2	0.3	0.1	0.1	0.1	0.2
33	J83067	0.5	0.3	0.2	0.1	0.3	0.5
34	148032	0.5	0.3	0.2	0.2	0.3	0.5
35	H62467	0.3	0.2	0.2	0.1	0.1	0.3
36	J10306	0.4	0.2	0.1	0.1	0.3	0.4
37	185405	0.5	0.6	0.2	0.2	0.3	0.5
38	H88015	0.3	0.2	0.1	0.1	0.2	0.3
39	K04937	0.1	0.3	0.3	0.2	0.2	0.1
40	D0092	0.2	0.3	0.2	0.2	0.1	0.2

SL NO	OP NO/IP	CREATINI	NE (mg/ dl)	Liver Function Test (IU/L)				
	NO	_		SGOT	SGOT	SGPT	SGPT	
-		BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER	
1	109544	0.7	0.6	10	15	10	12	
2	159413	0.8	0.7	19	19	13	17	
3	J35977	1	0.8	14	9	5	9	
4	H94125	0.9	0.8	13	9	12	6	
5	J22144	0.8	0.7	22	19	41	25	
6	J70445	1.2	1	18	19	16	17	
7	007518(IP)	0.7	0.6	10	15	10	12	
8	J73469	0.9	0.8	12	15	12	32	
9	H77668	1.4	0.8	14	12	12	10	
10	G15638	0.9	0.8	14	16	6	12	
11	I10061	1.1	0.8	13	20	6	10	
12	J73797	0.9	1.2	14	16	6	20	
13	J65069	1.1	1.2	21	24	20	30	
14	J74063	0.8	0.9	14	18	9	12	
15	132409	0.9	0.7	16	13	13	13	
16	J65774	0.9	1.2	15	16	20	23	
17	J44905	0.9	0.7	16	17	23	16	
18	J64112	0.7	0.8	10	15	8	11	
19	I14459	0.8	0.7	12	18	8	12	
20	197794	1.1	0.9	11	15	12	13	
21	F91016	0.4	0.9	30	29	28	25	
22	J67779	0.8	0.9	20.6	13	14.6	3	
23	J69753	0.9	0.9	38	36	33	38	
24	H91904	1	1	9	13	10	12	
25	173928	0.8	0.9	19	18	8	10	
26	H15822	0.9	1	17	17	20	21	
27	G17963	1	1.2	12	9	15	10	
28	J77255	1	1.2	14	18	9	12	
29	J57078	0.6	0.8	35	32	37	34	
30	J75796	1.1	0.9	13	21	21	28	
31	J73061	1	1	17	20	16	15	
32	J64099	1	1	21	15	13	20	
33	J83067	0.6	1.2	24	25	9	12	
34	148032	1	1.2	16	20	9	10	
35	H62467	1.8	1.2	18	19	17	20	
36	J10306	0.8	0.3	18	20	15	18	
37	185405	0.8	0.9	15	12	17	8	
38	H88015	0.7	0.8	13	20	13	19	
39	K04937	0.9	0.8	23	25	18	20	
40	D0092	0.9	0.8	18	24	17	22	

SL	OP NO/IP	ALKALINE						
NO	NO	PHOSPHATASE		SERUM CALCIUM		SERUM PHOSPHORUS (mgm /dl)		
		(IU/ BEFORE	L) AFTER	(mgn BEFORE	n /dl) AFTER	(mgr BEFORE	<u>n /dl)</u> AFTER	
1	109544	72	61	<u>9</u>	8.8	3.8	3.6	
2	159413	95	84	8.2	8.5	3.8	3.9	
3	J35977	159	132	9.9	8.9	3.9	4	
4	H94125	91	92	9.7	9	3.8	3.9	
5	J22144	84	87	9.6	10.2	4	3.9	
6	J70445	68	70	10.1	10.2	3.8	3.7	
7	007518(IP)	72	61	9	8.8	4	4.1	
8	J73469	82	93	7.3	9.7	3.7	3.9	
9	H77668	100	91	9	9.1	4	4	
10	G15638	110	98	9.3	9.4	3.8	3.9	
11	110061	96	110	8.4	8.2	3.8	3.5	
12	J73797	120	104	9	9.4	3.1	3.1	
13	J65069	57	90	9.7	9	3.8	4	
14	J74063	117	140	9.5	9.5	3.8	3.6	
15	132409	59	62	9.4	8.5	3.4	3.4	
16	J65774	99	110	9.4	9.6	4	4.2	
17	J44905	99	106	9.6	10.5	3.8	3.9	
18	J64112	70	68	9.4	10	3	3.4	
19	I14459	60	120	8.4	9	3.8	3.5	
20	197794	125	117	9.4	9.3	4	3.9	
21	F91016	110	120	9.8	9.8	3.4	3.5	
22	J67779	61	56	9.6	10.4	3.8	3.5	
23	J69753	105	110	9.3	9.4	3.8	3.6	
24	H91904	88	95	9.7	8.9	3.8	3.8	
25	173928	95	110	8	8.2	3.8	3.4	
26	H15822	105	102	9.1	9.1	3.2	3	
27	G17963	120	140	9.7	9.5	3.8	3.5	
28	J77255	78	120	9	9.2	3.4	3.2	
29	J57078	94	102	9.1	9	3.8	3.6	
30	J75796	59	54	10	9.3	4	4.2	
31	J73061	87	110	9.5	9.4	4	3.9	
32	J64099	117	102	9.3	8.9	3.4	3.8	
33	J83067	108	110	10	10.1	4	4.1	
34	148032	84	110	10	10.1	3.8	4	
35	H62467	110	120	9.8	9.4	3.4	3.2	
36	J10306	146	152	10	9.8	3.8	3.4	
37	185405	90	91	10.2	9.2	4	4.1	
38	H88015	61	90	10.1	9.8	4	4.1	
39	K04937	140	184	9	9.1	3.4	3.2	
40	D0092	112	120	8.5	8.9	3.4	3.5	

SL NO	OP NO/IP NO		JRIC ACID g/dl)	SERUM PROTIEN (gms / dl)		SERUM ALBUMINE (gms / dl)		
		BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER	
1	109544	2.7	3.8	7.7	7.7	3.3	3.8	
2	159413	4.2	4.5	6.7	6.6	3.1	3.1	
3	J35977	4.2	4.9	7.2	6.8	3.7	3.2	
4	H94125	4.2	4.1	7.8	7.7	4.2	3.9	
5	J22144	4.2	4	6.8	7	4.2	3.8	
6	J70445	5.4	5	7.9	7.8	4.1	4.1	
7	007518(IP)	2.7	3.8	7.7	7.7	3.3	3.8	
8	J73469	4	5.4	6.6	6.6	3.8	3.7	
9	H77668	6.5	6.2	7.5	7.1	4	3.6	
10	G15638	4.6	4.8	7.6	7.9	4.1	4	
11	I10061	7.4	7	7.7	7.5	3.5	3.2	
12	J73797	4.5	4	7	7.9	4.2	4	
13	J65069	5.5	5	8.2	8	4.5	4.2	
14	J74063	6.1	6	7.6	7.2	3.6	3.4	
15	132409	3.6	4	7	6.6	3.7	3.6	
16	J65774	5.2	4.2	7	7.2	4	4.2	
17	J44905	4.2	3.8	7.2	7.7	4.2	4	
18	J64112	4.9	5.6	7.4	8.3	3	3.7	
19	I14459	3.3	3.1	7.5	7	3.9	3.5	
20	197794	7.4	7.2	7.3	7.1	3.7	3.5	
21	F91016	3.9	4	7.4	7.3	4.5	4.4	
22	J67779	6	5.7	7.4	7.4	4	4.1	
23	J69753	3.4	3	7.6	7.5	3.8	3.4	
24	H91904	4.7	5.1	6.5	7.3	3.6	3.5	
25	173928	4.9	4	8.3	8	3.4	3.5	
26	H15822	4	4.1	7.8	7.5	4.2	4.2	
27	G17963	4.7	4.5	6.7	6.5	3.6	3.5	
28	J77255	3.7	3.5	7.3	8	3.8	3.5	
29	J57078	3.9	4	0.5	7.5	4	4.2	
30	J75796	3.9	4.6	7.2	7.5	4.2	4	
31	J73061	4.7	4.5	7.4	7.2	3.7	3.5	
32	J64099	5.6	5.9	7.8	7.5	4.3	3.7	
33	J83067	4.8	4.7	7.4	7.2	3.5	3.2	
34	148032	4.9	4.8	7.5	7.4	4	4.2	
35	H62467	3.8	3.4	7.4	7.8	4	4.1	
36	J10306	3.4	3.3	8	7.8	3.7	3.5	
37	185405	3.9	4.6	7.3	6.3	4.1	3.7	
38	H88015	3	3.8	8.1	8	4.1	4.2	
39	K04937	3.2	3.8	7.4	7.8	3.8	3.9	
40	D0092	3	2.9	7	7.3	3.8	3.7	

SL NO	OP NO/IP NO	SERUM G (gm		URINE ANALYSIS					
				URINE	URINE	FASTING	FASTING		
		BEFORE	AFTER	ALBUMIN	ALBUMIN	BEFORE	AFTER		
1	109544	4.7	3.9	nil	nil	Nil	Nil		
2	159413	3.5	3.5	nil	nil	Nil	Nil		
3	J35977	3.4	3.6	nil	nil	Nil	Nil		
4	H94125	3.6	3.8	nil	nil	Nil	Nil		
5	J22144	3.3	3.2	nil	nil	Nil	Nil		
6	J70445	3.8	3.5	nil	nil	Nil	Nil		
7	007518(IP)	4.7	3.9	nil	nil	Nil	Nil		
8	J73469	2.9	2.9	nil	nil	nil	Nil		
9	H77668	3.5	3.5	nil	nil	nil	Nil		
10	G15638	3.5	3.9	nil	nil	nil	Nil		
11	I10061	4.2	4	nil	nil	nil	Nil		
12	J73797	3.9	3	nil	nil	nil	Nil		
13	J65069	3.7	3	nil	nil	nil	Nil		
14	J74063	4	3.8	nil	nil	nil	Nil		
15	132409	3.4	3	nil	nil	nil	Nil		
16	J65774	3	3.4	nil	nil	nil	Nil		
17	J44905	3	3.7	nil	nil	nil	Nil		
18	J64112	3.9	4.6	nil	nil	nil	Nil		
19	I14459	3.6	3.7	nil	nil	nil	Nil		
20	197794	3.6	3	nil	nil	nil	Nil		
21	F91016	2.8	3	nil	nil	nil	Nil		
22	J67779	3.1	3.3	nil	nil	nil	Nil		
23	J69753	3.8	3.6	nil	nil	nil	Nil		
24	H91904	3.1	3.8	nil	nil	nil	Nil		
25	173928	4.9	4.5	nil	nil	nil	Nil		
26	H15822	2.9	2.2	nil	nil	nil	Nil		
27	G17963	3.1	3	nil	nil	nil	Nil		
28	J77255	3.6	2.9	nil	nil	nil	Nil		
29	J57078	3.2	3.1	nil	nil	nil	Nil		
30	J75796	3.5	3.5	nil	nil	nil	Nil		
31	J73061	3.7	3.4	nil	nil	nil	Nil		
32	J64099	3.6	3.8	nil	nil	nil	Nil		
33	J83067	3.9	3.7	nil	nil	nil	Nil		
34	148032	2.6	2.8	nil	nil	nil	Nil		
35	H62467	3.9	3.8	nil	nil	nil	Nil		
36	J10306	4.3	4.2	nil	nil	nil	Nil		
37	185405	3.2	2.6	nil	nil	nil	Nil		
38	H88015	4	4	nil	nil	nil	Nil		
39	K04937	3	3.2	nil	nil	nil	Nil		
40	D0092	3.6	3.6	nil	nil	nil	Nil		

SL	OP NO/IP	URINE ANALYSIS					
Ν	NO	POST		PUS	PUS		
0		PRANDIA	POST	CELLS	CELLS	EPITHELIL	EPITHELIL
		L	PRANDIA	BEFOR	AFTE	CELLS	CELLS
1	109544	BEFORE	L AFTER Nil	E 4 to 6	R 2 to 4	BEFORE	AFTER
1		nil			2 to4	1 to 2	2 to 4
2	159413	nil	Nil	1 to 2	4 to 6	1 to 2	4 to 6
3	J35977	nil	Nil	3 to4	1 to 2	1 to 2	1 to 2
4	H94125	nil	Nil	2 to 4	3 to 5	1 to 2	3 to 5
5	J22144	nil	Nil	2 to3	2 to 3	2 to 3	1 to 2
6	J70445	nil	Nil	1 to2	1 to 2	1 to 2	1 to 2
7	007518(IP)	nil	Nil	3 to 5	1 to 2	1 to 2	1 to 2
8	J73469	nil	Nil	1 to 2	6 to 8	1 to 2	10 to 12
9	H77668	nil	Nil	2 to 4	3 to 5	1 to 2	1 to 2
10	G15638	nil	Nil	2 to 4	3 to 5	1 to 2	1 to 2
11	110061	nil	Nil	1 to 2	1 to 3	1 to 2	1 to 3
12	J73797	nil	Nil	2 to 4	1 to2	1 to 2	1 to 2
13	J65069	nil	Nil	2 to 4	1 to 2	1 to 2	1 to 2
14	J74063	nil	Nil	1 to 2	1 to 2	1 to 2	1 to 3
15	132409	nil	Nil	3 to 5	1 to 2	2 to 4	1 to 2
16	J65774	nil	Nil	3 to 4	1 to 2	3 to4	1 to 2
17	J44905	nil	nil	3 to 4	1 to 3	3 to 4	1 to 3
18	J64112	nil	nil	3 to 4	1 to 2	1 to 2	1 to 2
19	I14459	nil	nil	8 to 10	2 to 4	3 to 4	1 to 2
20	197794	nil	nil	10 to 12	6 to 8	1 to 2	1 to 2
21	F91016	nil	nil	3 to 5	1 to 2	1 to 3	1 to 2
22	J67779	nil	nil	1 to 2	3 to 5	1 to 2	3 to 5
23	J69753	nil	nil	1to 2	1 to 2	1 to 2	1 to 2
24	H91904	nil	nil	2 to 4	1 to 2	1 to 2	1 to 2
25	173928	nil	nil	3 to 4	1 to 2	1 to 2	1 to 2
26	H15822	nil	nil	1 to 2	1 to 2	1 to 2	1 to 3
27	G17963	nil	nil	3 to 5	1 to 2	1 to 2	1 to 2
28	J77255	nil	nil	2 to 4	1 to 2	2 to 4	1 to 2
29	J57078	nil	nil	2 to 4	1 to 2	1 to 2	1 to 3
30	J75796	nil	nil	2 to 3	1 to 2	2 to 4	1 to2
31	J73061	nil	nil	1 to 2	1 to 2	1 to 2	1 to 2
32	J64099	nil	nil	1 to 2	2 to 4	1 to 2	2 to 4
33	J83067	nil	nil	2 to 4	1 to2	2 to 4	1 to 2
34	148032	nil	nil	2 to4	1 to 2	2 to 4	1 to 2
35	H62467	nil	nil	3 to 5	1 to 2	3 to4	1 to 2
36	J10306	nil	nil	4 to 6	1to 4	1 to 2	1 to 2
37	185405	nil	nil	3 to 5	2 to 4	2 to 4	2 to 4
38	H88015	nil	nil	1 to 2	1 to 2	3 to 5	1 to 2
39	K04937	nil	nil	3 to 4	1 to 2	1 to 2	1 to 2
40	D0092	nil	nil	3 to 4	1to2	1 to 3	1 to 2

#### DISCUSSION

The main aim of this study was to evaluate the Therapeutic effect of the trial drug **MERUGULLI THYLAM** (Internal medicine) to reduce pain, swelling and restricted joint movements in the disease VALI AZHAL KEELVAYU (Rheumatoid arthritis) in which, there occur a derangement of Vatha thathu and Pitha thathu.

Vatham, Pitham, Kabam the three vital humours (uyir thathukkal) are responsible for the physiological functions of udal thathukkal (7 body constituents).Life style modifications (Food and deeds, stress, mental and physical environmental) causes derangement of vital humours resulting in vitiation of uyir thathukkal called mukkutram (disease).

Derangement of the vatham leads to impairment in Udal thathukkal and in turn produces symptoms like pricking pain, body ache, mental stress, difficulty in flexion and extension of joints.

Pitham maintains the body temperature and has the basic function of production and maintenance of the internal environment (Homeostasis). Hence Pitham when deranged produces symptoms like fever and changes in the internal environment. The vitiates vatham and pitham causes vatha noigal ,one among is vali azhalkeelvayu. The signs and symptom of valiazhal keelvayu may be correlated with RA in that of modern scientific system of medicine.

Siddha literature THERAN MARUTHUVA BHARATHAM predicts the fact that we should choose medicines for diseases and not diseases for medicine.

Dryness, Roughness, coldness and subtleness are one among the basic qualities of Vatham. Hence a drug possesses the opposite qualities like Heaviness, hotness and solidness would rectify the derangement of vatham. According to siddha philosophy PUNGENT taste balances Vatham and sweet taste balances pitham.

The ingredients of the trial drug Merugulli thylam posses Veppa Veeriyam (Hot potency) naturally and predominantly contains Kaarpu suvai(Pungent taste). Hence the trial drug expected to balance and rectify the deranged vatham.

Hence the trial drug which possess anti-vatha property as mentioned in Siddha literature were selected and the trial drug was prepared in the Gunapadam laboratory of National Institute of Siddha,Chennai. After getting proper authentication of raw drugs from the Assistant professor of Medicinal Botany at NIS, Chennai 47, The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

Standardization of the trial drug through biochemical analysis was carried out.

The Biochemical qualitative and quantitative analysis were done at the biochemistry lab of NIS. It revealed the presence of effective minerals like calcium, iron etc.

The Drug standardization and TLC, HPTLC were carried out by Captain Srinivasa Murthy Regional Ayurveda Drug Development Institute, Arumbakkam, Chennai and Test for Aflatoxin were done by Regional Research Institute of Unani Medicine, Royapuram respectively.

The clinical study was conducted with a well defined protocol and a proper proforma after the approval of the Institutional Ethical Committee, the clinical study was registered in CTRI (Clinical Trial Registry -India). After that the enrolment of patients was started.

### IEC NO: NIS/IEC/2016/11-07/14.10.2016

#### CTRI NO: CTRI/2018/03/012365

After screening patients reporting at the OPD of department of Maruthuvam, 40 cases of both genders were selected for induction to the trial. Before enrolment into the trial the informed consent was obtained from the patients.

Among the 40 patients 39 were OPD patients and the remaining one was an IPD patient. For In-Patient, who was not in a situation to stay in the hospital for a long time, was advised to attend the Out-Patient Department of Maruthuvam .

From the First day on wards, the patients were treated with trial drug Merugulli thylam (Internal medicine) 9 ml/dose -3 days morning only in empty stomach (2 days drug holiday) this fashion of drug administration was followed for 45 days. Patients were instructed to take the medicines regularly and advised to follow pathiyam (avoid tamarind, tubers, etc) and advised to avoid cold exposure. Out-Patients were asked to visit the hospital once in 5 days to collect the drug and as well as for clinical assessment and the clinical assessment was done on 0<sup>th</sup> day, 5<sup>th</sup> day, 10<sup>th</sup> day, 15<sup>th</sup> day , 20<sup>th</sup> day, 25<sup>th</sup> day, 30<sup>th</sup> day, 35<sup>th</sup> day, 40<sup>th</sup> day, 45<sup>th</sup> day.

After the treatment, the patients were advised to visit the Out-Patient department of Maruthuvam for another 2 months for follow-up without trial drug.

#### The results observed during the study period were discussed on the basis of below.

# **OBSERVATION AND RESULTS**

#### AGE GROUP

In Age group

4 (10%) cases affected patients came under the age group between 20-30 years.14 (35%) cases fall under the age group between 31-40 years.15 (37.5%) cases were between 41-50 years and 7 (17.5%) cases were between 51-60 yrs. Inference:

Inference:

Most of the cases were affected in the age group of 41-50 yrs.

#### GENDER

According to the Gender Among the 40 patients selected, the disease (R.A) was found to be higher in females 33 cases (82.5%) and lower in males 7 cases (17.5%).

Inference:

The prevalence was more in females than in Males. The male female ratio is 1:8.

The most prominent theory about the development of RA being more common in women is associated with changes in the levels of sex hormones, including oestrogen and progesterone which have critical roles in the inflammatory response, and in the overall regulation of the immune system.

### SOCIO-ECONOMIC STATUS

In socio-economic status the incidence of the disease was as follows,

In Middle income group	-	29 cases(72.5%)
The low income group	-	10 cases(25%)
Higher income group	-	1 case (2.5%)

Inference:

In this study, most of the cases - 29 cases (72.5%) under middle income group

### **MENSTURAL HISTORY**

Among 40 cases observed, out of 33 females, 8(24.24%) females attained menopause, 2 (6.06%) females in hysterectomy status.

The risk of developing RA is hightest in peri and postmenopausal women<sup>(4)</sup>.

#### MARITAL STATUS

Among 40 cases 39 (97.5%) got married and 1 case (2.5%) not married.

#### **EDUCATIONAL STATUS**

Among 40 cases 24 cases (60%) were literate and 16 cases (40%) were ill literate.

### **INCIDENCE DUE TO FAMILIAL INVOLVEMENT HISTORY:**

Among 40 cases, 39 (97.5%)cases did not have any familial history.1 (2.5%) case had the incidence of the disease in their relationship.

In this study most of the cases 39 (97.5%) cases did not have familial history.

### **OCCUPATIONAL DISTRIBUTION**

In Occupational distribution Among 40 cases, 30cases (75%) were home maker, 1case (2.5%) was Student,1 Case (2.5%) was Beautician, 4 Cases (10%) were cooli, 1 Case (2.5%) was Farmer,2 Cases (5%) were Driver and 1 Case (2.5%) was Tailor.

In this study 30 cases(75%) were Home maker.

# DIET

In diet out of 40 patients, 30 cases were Non vegetarian (75%). They were higher than the vegetarian 10 cases (25%).

## Inference:

In this study most of the cases were observed to be non vegetarians.

Higher plasma levels of fat derived hormones leptin, adiponectin and visfatin are found to be a modulation of the inflammatory environment in patients with RA. More over prevalence of RA is 50% greater in non vegetarians <sup>(5)</sup>.

## OBESITY

In my study Out of 40 cases 5 cases 12.5 % were Obese, 35 cases 87.5 % were belongs to normal weight.

## Inference:

In Obesity there seems to be an increase in the inflammatory markers in the blood, most of them produced by the WAT (White Adipose Tissue) in RA

#### TREATMENTAL HISTORY OTHER THAN SIDDHA TREATMENT:

9 cases (22.5%) due to adverse effects of drugs (like NSAIDS, Steroids), 2 cases (5%) were referred from rheumatologist, 4 cases (10%) were not undergone any treatment before

Among 40 patients, 25 (62.5%) cases came to Siddha treatment due to fear for adverse effects in other system of medicine.

## THINAI

In Thinai Amoug the 40 cases, 37 (92.5%) cases were from Neithal thinai, 2 (5%) cases were from Kurinji and 1 (2.5%) case was Marutham.

In Siddha literatures; it is mentioned that vaatha diseases are common in Neithal nilam.

"நெய்தனில மேலுவர்ப்பை நீங்கா துநினுமது வெய்தனில மேதங்கு வீடாகும்- நொய்தீன் மருங்குடலை முக்காக்கி வல்லுறுப்பைவீக்கும் கருங்குடலைக் கீழிறக்குங் காண்" - பதார்த்த குண சிந்தாமணி

This study also revealed the majority cases were from in Neithal thinai.

# PARUVA KAALAM

In Paruva Kaalam (Season) Out of 40 cases, 26 cases(65%) were included in Koothirkaalam and 12 (30%) cases were included in Munpanikaalam, 2% (5) in Pinpani kalam.

- According to Siddha literature in Kaar kalam Vali azhal keelvayu like Vatha diseases may occur at greater incidence. In Muthuvenil Kaalam the disease may worsen than before
- According to a recent research, predictors of radiographic progression unveiled a distinct relationship between RA progression and seasonal onset postulate that this could be as a result of either a Vitamin D deficiency or environmental factors such as winter viruses, influencing protein citrullination especially winter and spring<sup>(6)</sup>.

#### KOSANGAL

Among 40 cases, Vignanamaya kosam was affected in all cases due to pain and restricted of movements of the minor and major joints. Annamaya kosam was affected in 31 cases (77.5%) due to loss of appetite. Pranamaya kosam was affected in 5 cases(12.5%) due to dyspnoea on exertion. Manomaya kosam was affected in 26 cases (65%) due to mental depression. Ananthamaya kosam affected in 3 cases (7.5%) duo to disturbed sexual life owing to pain, restriction of movements and mental depression.

- RA impacts on the sexual lives of a large minority of patients. This limitation was in general symptom-related, fatigue, pain and reduced joint function being the primary culprits <sup>(7)</sup>.
- Depression is more commen in patients with Rheumatoid arthritis than in healthy individuals.(Psychomatic Medicine 64:52-60(2002)) sighing was significantly and strongly related to patient's level of depression and non significant and less strongly related to their reported pain and number of flare days <sup>(8)</sup>.

## **GUNAM**

In Gunam, 38 (95%) of cases had Raso gunam and 2 (5%) of cases had Thamo gunam.

# **BODY CONSTITUTION**

In Body constitution Out of 40 cases, 35 cases (87.5%) were came under Thontha thegi and 5 cases (12.5%) were came under kaba thegi.

#### **CONDITION OF MUKKUTTRAM:**

#### **Derangement in vatha kutram:**

Viyaanan and Samanan were affected in all 40 cases (100%) which resulted in pain, swelling, morning stiffness and restricted movements of the joints. Praanan was affected in 5 cases (12.5%) which resulted in dyspnoea on exertion. Abaanan was affected in 37 cases (92.5%) which resulted in constipation. naagan was affected in 1 case(2.5%) which resulted in diminished vision. Devathathan was affected in 28 cases (70%) which resulted in lethargy & disturbed sleep. Uthanan, Koorman, Kirukaran, and Dhananjeyan remained normal in all cases.

#### **Derangement in pitha kutram:**

In Pitham Among 40 cases, Saathagam was affected in all 19 cases (47.5%) which indicates difficulty in walking, difficulty to perform regular duties. Ranjagam was affected in 27 cases (67.5%) which resulted in pallor of conjunctiva. Analagam was affected in 31 cases (77.5%) which resulted loss of appetite.

#### Derangement in kaba kutram:

Among 40 cases, Avalambagam and santhigam were affected in all the 40 Cases (100%) due to pain in joints Klethagam was affected in 31 cases(77.5%) which caused by loss of appetite. Tharpagam was affected in 1 case(2.5%) due to burning sensation of eyes.

#### INCIDENCE WITH REFERENCE TO THE ENVAGAI THERVU

In Envagai Thervu, Naadi : Under the study of naadi, all the 40 cases showed Thontha naadi. Sparisam was affected in 40 cases (100%) as they had swelling, tenderness in joints with local heat. Vizhi was affected in 27 cases (67.5%) as it showed pale conjunctiva. Naa was affected in 27 cases(67.5%) as it showed coating of tongue and pallor. Malam was affected in 37 cases (92.5%) leading to constipation. Mozhi ,niram and Moothiram were found to be normal in all 40 cases.

# INCIDENCE WITH REFERENCE TO THE NAADI TYPE

While seeing the Naadi, Among 40 cases showed Thontha naadi Vatha pitha naadi was found in 32 cases (80%), Pitha vatha naadi was found in 3 cases (7.5%), Pitha kaba naadi was found in 1 cases (2.5%), Vaatha kaba naadi was found in 2 cases (5%) and Kaba vatha naadi was found in 2 cases (5%).

In this study, Vatha pitha naadi was predominant in 32 cases(80%).

## **INCIDENCE WITH REFERENCE TO THE NEIKKURI**

Among 40 cases ,5 cases (12.5%) had Vatham pattern of Neikuri i.e. Aravena neendathu (Spreading like a snake) 35 cases (87.5%) had Kapham pattern of Neikuri, i.e Muththothu Ninrathu(Stands like a pearl.)

In this study, Most of the cases (87.5%) had Kapham pattern of Neikuri.

#### INCIDENCE WITH REFERENCE TO THE UDAL THAATHUKKAL

Among 40 cases, **Saaram** was affected in all 40 (100%) cases that produced the symptoms like lethargy. **Senneer** was affected in 27 cases (67.5%) that produced the symptoms like loss of strength and loss of appetite.

**Oon** was affected in all 40 (100%) cases that produced the symptoms like swelling, morning stiffness of affected joints and pain in affected joints. **Kozhuppu** was affected in all 40 (100%) cases that produced the symptoms like swelling in the affected joints particularly interphalangeal, difficulty in movements of affected joints.

**Enbu** was affected in all 40 cases (100%) was affected in all 40 (100%) cases that produced the symptoms like swelling, redness of affected joints, deformities and restriction in movements. **Moolai** was affected in all 40 (100%) cases that produced the symptoms like swelling in the affected joints particularly interphalangeal joints.

Sukkilam and suronitham were not affected in all the cases concerned to the disease.

### IN KANMENDRIUM,

Kai and Kaal were affected in 40 cases (100%) due to pain, swelling, morning stiffness and deformities. Eruvai was affected in 37 (92.5%) cases.

## **DURATION OF ILLNESS**

In Duration of illness, In this study, about 9 (22.5%) cases had upto 1 yr duration, 11(27.5%) cases had 1 to 2 yrs of duration,13 (32.5%) cases had 2-5 yrs of duration, 5 (12.5%) cases had 5 to 7 yrs of duration and 1 (2.5%) cases had 7-10 yrs and another one case had 10-15 yrs of duration.

## MODE OF ONSET

According to the mode of onset In my study 30 (75%) cases had Gradual onset of illness, 10 (25%) cases had Sudden onset of illness.

### **INVOLVEMENT OF JOINTS**

Cervical vertebrae were involved before treatment in 15 (37.5%) cases after treatment it was in 5 cases (12.5%).Elbow joint were involved in before treatment in 35 case (87.5%). After treatment it was in 10 cases (25%).

Wrist joint and ankle joint were involved in 39 cases (97.5%), 35 cases (87.5%) respectively. After treatment it was 12 cases (30%), and 24 cases (60%). MCP joints were involved in 37 cases (92.5%), after treatment it was in 19 cases (47.5%)

Knee joint was involved in 36 cases (90%). After treatment it was 20 cases (50%), PIP joint were involved in 40 cases (100%) before treatment, after it was in 25 cases (62.5%).

Lumbosacral joint was affected in 14 cases (35%) before treatment after treatment it was in 8 cases (20%). (25%) 10 cases were affected in hip joint before treatment, after it was in 5 cases (12.5%).

## **CLINICAL SYMPTOMS**

#### **Observation with reference to Clinical symptoms**

#### Pain

Before treatment all 40 cases (100%) had pain, After treatment it was reduced into 24 cases (60%).

## Swelling in joints

All 40 cases (100%) had swelling before treatment, No one had swelling after treatment.

# **Morning stiffness**

All 40 cases (100%) had morning stiffiness before treatment, It was reduced to (2 cases) 5%.

## Tenderness,

All 40 cases (100%) had tenderness before treatment, after treatment it was reduced to 0 case (0%)

### Fever

Before treatment Fever was found in 2 cases (5%) which was relieved after treatment.

## **Restricted movements**.

All 40 cases (100%) had restricted movements before treatment, after treatment it was reduced to 10 cases (25%).

## Polyarthralgia

Before treatment 40 cases (100%) had polyarthralgia, after treatment it was reduced to 25 cases (62.5%).

#### Deformities

Deformities remained the same before and after treatment in 19 cases (47.5%) Among the Deformities in this study, 11(27.5%) cases had Spindle shaped deformity, 7 (17.5%) cases had Button hole derormity, 1 (2.5%) cases had Swan neck deformity.

#### Anorexia

Before treatment 31 cases (77.5%) had Anorexia, After treatment no cases were reported with anorexia.

#### **PRIMARY OUTCOME**

#### PAIN ASSESSMENT SCALE

In this study, 25 cases (62.5%) had severe pain, 15(37.5%) cases had Moderate pain. After treatment no one had severe pain, one (2.5%) case had Moderate pain, 23(57.5%) cases had Mild pain, 16 (40%) cases had no pain.

The mean $\pm$  standard deviation of pain score before and after treatment were  $7 \pm 1.22$ and  $1.3\pm1.24$  respectively which is **statistically significant** (p<0.001) The analysis revealed that significant reduction of pain with the trial drug i.e. there is **81.4%** reduction in pain compared to start of the treatment.

#### FUNCTIONAL ABILITY GRADATION

Grade I -	Fit for all activities
-----------	------------------------

- Grade II Mild restriction
- Grade III Moderate restriction
- Grade IV Confined to chair or bed ridden

Among 40 cases, before treatment 4 (10%) cases were in grade IV, 19 (47.5%) cases were in Grade III. After treatment no one came under Grade IV and III. Before treatment 17(42.5%) cases were in Grade II after treatment 10(25%) cases under Grade II. After treatment 30 cases (75%) came under Grade I

#### **IMPROVEMENT IN FUNCTIONAL ABILITY ASSESSMENT OF PATIENTS:**

As per Cross tabulation, Before treatment 4 cases (10%) came under grade IV after treatment 1 case (2.5%) under grade I and 3 cases (7.5%) under Grade II. Before treatment 19 cases (47.5%) came under Grade III after treatment 12 cases (30%) came under grade I

and 7 cases (17.5%) came under grade II, Before treatment 17(42.5%) cases in Grade II after treatment all 17 (42.5%) cases came under Grade I.

It revealed that over all good improvement

#### SECONDARY OUTCOME OBSERVATION

#### LABORATORY INVESTIGATIONS

#### Observation with reference to RA factor.

Among 27 cases (67.5%) who are positive at commencement of the treatment 9 (33.3%) were screened negative and 18 (45%) cases remained positive for RA factor after the treatment.

Although the diagnosis of RA is a clinical one, rheumatoid factor is an important prognostic marker, those who test positive are more likely to have a worse prognosis with respect to joint destruction, physical/ occupational disability and quality of life in general.

#### **Observation with reference to C Reactive Protein**

Among 25 cases (62.5%) who are positive at commencement of the treatment 6(24%) were screened negative and 19 (47.5%) cases remained positive for C reactive protein after the treatment.

#### **Observation with reference to ASO titre**

Among 10 cases who are positive at commencement of the treatment 2(20%) cases were screened negative and 8 (20%) cases remained positive for ASO titre after the treatment.

#### HAEMOGLOBIN

Among 40 cases, there was no significant changes after the treatment statistically.

#### **ERYTHROCYTE SEDIMENTATION RATE (ESR)**

The analysis revealed that there is 49.7% reduction in ESR  $\frac{1}{2}$  HR

and 52.44% reduction in ESR 1 HR compared to start of the treatment.

The mean  $\pm$  standard deviation before treatment is 32.02 $\pm$  19.75 and after treatment is 16.1  $\pm$ 10.91 for  $\frac{1}{2}$  hr. The analysis revealed that there is 49.7% reduction in ESR  $\frac{1}{2}$  HR compared to start of the treatment.

The mean  $\pm$  standard deviation before treatment is 57.97 $\pm$  32.54 and after treatment is 27.57  $\pm$ 19.52 for 1 hr. The analysis revels that there is 52.44% reduction in ESR 1 HR compared to start of the treatment.

The statistical analysis reveals that there has been a **significant reduction in ESR** value after treatment indicating the control over the inflammatory process of the disease.

The erythrocyte sedimentation rate (ESR) or C reactive protein (CRP) -Acute phase reactant is measured in RA either, both of which are elevated during active disease as a sign of inflammation.

#### **BIOCHEMICAL ANALYSIS**

Qualitative analysis of MERUGULLI THYLAM done in NIS biochemical lab revealed that Merugulli thylam contains Calcium, Silicate, Iron, Phosphate, Alkaloids, Starch etc.

S.NO	PARAMETERS	RESULTS
1	Refractive index	1.4752
2	Acid value	9.41
3	Saponification Value	181.45
4	Peroxide Value	5.36
5	Iodine value	83.11
6	Weight	0.964

#### **Standardization Report**

#### **TLC & HPTLC**

HPTLC finger print of Merugulli thylam could serve as a marker and which is responsible for expression of its biological and clinical actions.

- HPTLC was carried out in UV at 254 nm, UV at 366 nm to establish the finger printing profile and to show the possibly active phytochemical constituents.
- In 254 nm UV the peak corresponds to the Rf values 56.51% has maximum peak area of 4140.6 AU(area 43.84%) is a marker.
- In 366 nm UV the peak corresponds to the Rf values 83.03% has maximum peak area of 2547.0 AU(area 80%) is a marker.
- > No Aflatoxins were detected in Merugulli thylam.

#### **SUMMARY**

The aim of the study was to evaluate the efficacy of the drug MERUGULLI THYLAM (Internal) in Vali azhal keelvayu.

Before initiating the clinical trial, approval was got from the Institutional Ethical Committee for conducting the clinical study by submitting the well defined protocol and proforma. **IEC NO: NIS/IEC/2016/11-07/14.10.2016** 

Then the clinical trial was registered in CTRI(Clinical Trial Registry -India). After that the enrolment of patients was started.

#### CTRI NO: CTRI/2018/03/012365

- The raw drugs were authenticated by the Assistant Professor, Medicinal Botany and the trial drug was prepared by the investigator in the Gunapadam lab of National Institute of Siddha as per the Standard Operating Procedure mentioned in the protocol.
- Bio chemical studies were done at the bio chemistry lab of National Institute of Siddha, The standardization and TLC &HPTLC were done at the Captain Srinivasa Murthy Regional Ayurveda Drug Development Institute, Arumbakkam, Chennai.(as per letter of CSMRADDI) And detection of aflatoxin were done in Regional Research Institute of Unani Medicine, Royapuram respectively.
- Among the 105 cases screened at the OPD of department of Maruthuvam NIS, 40 cases were recruited for the trial as per the inclusion and exclusion criteria.
- Clinical diagnosis of valiazhal keelvayu was made by Siddha and Modern methodology.
- Before inducement into the trial informed consent was obtained from the patients. Out of the 40 cases 39 cases were treated in OPD and 1 case in IPD.
- The trial medicine selected for Internal treatment was MERUGULLI THYLAM 9 ml/dose morning only in empty stomach with the adjuvant hot water referred under Siddha literature Theraiyar Thylavarga Surukkam.
- During the treatment period of 45 days the trial drug MERUGULLI THYLAM (internal) is given for 3 days followed by a re dieting (drug holiday) of 2 days. Likewise the medicine is given till the end of the course.

- Diet restriction was strictly followed during the period of drug administration as well as re dieting period (Diet free of salt, coconut, horse gram etc) as per noted in the form IV (Dietary advice form).
- Required lab investigations were carried out before and after the treatment and the data was recorded in the proforma.
- Clinical assessment was done daily in IP patient and OP patients it was assessed once in 5 days.
- During the study period, there was no event of any adverse reactions owing to the drug or disease.
- In these studies out of 40 cases 81.4% of cases showed reduction in pain. There was improvement in other clinical symptoms before and after treatment revealing the effect of drug in reducing the pain and other clinical symptoms. Thus improvement of the patients in their daily life activities.
- As per the Siddha Literature and modern science reviews and research articles, the ingredients of the trial drugs were found to have the property of controlling the Vatha diseases, some drugs exhibited anti inflammatory, anti analgesic activities owing to the disease manifestations.
- Clinical Lab parameters there was reduction in RA factor, CRP and ASO titre [RA factor- 27 cases (67.5%) positive at commencement of the treatment 9 (33.3%) were screened negative after the treatment, CRP-25 cases (62.5%) positive at commencement of the treatment 6(24%) were screened negative after the treatment, ASO titre -10 cases positive at commencement of the treatment of the treatment 2(20%) cases were screened negative after the treatment] and ESR 49.7% reduction in ESR ½ HR and 52.44% reduction in ESR 1 HR which showed the therapeutic effect of the drug in controlling the disease to a greater extent.
- Statistical analysis showed significant reduction in pain scale and a significant reduction in ESR value after treatment indicating the control over the inflammatory process of the disease.
- Bio chemical analysis showed the precence if inevitable constituents like Iron,Calcium,Sulphur which played a role in repairing and preventing the joint damage in the disease.
- TLC & HPTLC HPTLC finger print of Merugulli thylam could serve as a marker and which is responsible for expression of its biological and clinical actions.

- HPTLC was carried out in UV at 254 nm, UV at 366 nm to establish the finger printing profile and to show the possibly active phyto chemical constituents.
- In 254 nm UV the peak corresponds to the Rf values 56.51% has maximum peak area of 4140.6 AU(area 43.84%) is a marker.
- In 366 nm UV the peak corresponds to the Rf values 83.03% % has maximum peak area of 2547.0 AU(area 80%) is a marker
- > No Aflatoxins were detected in Merugulli thylam.

#### CONCLUSION

- Statistical analysis [Paired "t" test] revealed that the therapeutic efficacy of the trial drug Merugulli thylam by showing, reduction in pain 81.4% of cases.
   (Universal pain assessment scale: *Ref: Clinical Manual for Nursing Practise National Institute of Health Warren Grant Magnuson Clinical Centre*)
- As per cross tabulation (vide table no.32) 30 cases (75%) came under Grade I (Fit for all activities) & 10 cases (25%) came under Grade II (Mild restriction) after the treatment. It revealed that 100% cases showed Good improvement in functional ability.
- There is a significant reduction in the elevated lab parameters [RA factor- 27 cases (67.5%) positive at commencement of the treatment 9 (33.3%) were screened negative after the treatment, CRP-25 cases (62.5%) positive at commencement of the treatment 6(24%) were screened negative after the treatment, ASO titre -10 cases positive at commencement of the treatment 2(20%) cases were screened negative after the treatment].
- The mean ± standard deviation before treatment is 32.02± 19.75 and after treatment is 16.1 ±10.91 for ESR ½ hr. The analysis revealed that there is 49.7% reduction in ESR ½ hr compared to start of the treatment.
- The mean ± standard deviation before treatment is 57.97± 32.54 and after treatment is 27.57 ±19.52 for ESR 1 hr. The analysis revels that there is 52.44% reduction in ESR 1 hr compared to start of the treatment.
- ✤ There were no adverse reactions complained during the trial period.
- The results of the clinical trial indicates that the trail drug MERUGULLI THYLAM is clinically effective, safe and also economical.
- Because of the encourage clinical outcome, the study may be further carried out with the same durg in large number of cases.

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# NATIONAL INSTITUTE OF SIDDHA AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

### DEPARTMENT OF MARUTHUVAM

# An Open Clinical study on "Merugulli thylam (Internal Medicine)" in the treatment of "Vali Azhal keel Vayu" (Rheumatoid Arthritis)

Principal Investigator: Dr.M.Suganthi

Reg.No.

#### FORM I - SCREENING & SELECTION PROFORMA

1. SERIAL NO:	2. OP /IP NO:
3. NAME:	4. AGE/GENDER:
5. OCCUPATION:	6. INCOME:

#### **INCLUSION CRITERIA**

Age between 20 and 60	Yes/No	Sex	M / F
Arthritis of three or more joints	Yes/No	Rheumatoid Factor- Positive	Yes / No
Symmetrical joint involvement	Yes/No	Anorexia	Yes/ No
Swelling especially in inter phalangeal joints	Yes/No	Low grade fever	Yes/No
Morning stiffness of joints > than an hour	Yes/No	Pain	Yes/No
Willingness to undergoRadiological & Laboratoty investigations	Yes/No	Willing to give consent	Yes/No

#### **EXCLUSION CRITERIA:**

Diabetes mellitus	Yes/No	Thyroidism(Hypo/Hyper)	Yes/No
Hypertention	Yes/No	Pregnancy and lactation	Yes/No
Cardiac disease	Yes/No	Any other serious illness like cancer	Yes/No
Tubercular Arthritis	Yes/No	Psoriatic Arthritis	Yes/ No
Gouty Arthritis	Yes/No	Osteoarthritis	Yes/ No

#### **ADMITTED TO TRAIL**

Yes: No:

If Yes: OPD IPD:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

#### NATIONAL INSTITUTE OF SIDDHA

#### AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI - 600 047.

#### DEPARTMENT OF MARUTHUVAM

An open Clinical study on "Merugulli Thylam (Internal Medicine)" in the treatment of "Vali Azhal Keel Vayu" (Rheumatoid Arthritis)

#### Principal Investigator: Dr.M.Suganthi

#### FORM II-A – HISTORY TAKING PROFORMA

STUDY NO:	OP / IP NO:
NAME:	AGE / GENDER:
ADDRESS:	CONTACT NO :
	<b>RELIGION : H / C / M / O.</b>
OCCUPATION:	INCOME:
MARITAL STATUS: 1. Married	2. Unmarried
DATE OF INTIAL ASSESSMENT:	
COMPLAINTS & DURATION:	

#### **PERSONAL HISTORY:**

PERSONAL HABITS	YES	NO		SPECIFY RATION	AMOUNT/Quantity
Smoking					
Tobacco Chewing					
Alcohol					
Whether this problem runs in family?         If yes, mention the relationship of affected person(s)		1. Yes	2. No		
		2			
DIETARY STYLE:		1. Vegetaria	an 2. Non-vegetarian		
MENSTURAL AND OB	STETRIC	HISTOR	Y:		

#### FORM II B

#### **GENERAL EXAMINATION:**

- 1. Body weight [Kg]
- 2. Height [cms]
- 3. Body Temperature [F]
- 4. Blood Pressure (mm/Hg)
- 5. Pulse Rate /min.
- 6. Heart Rate / min.
- 7. Respiratory Rate /min.
- Yes No 8. Pallor : 9. Jaundice : 10. Clubbing : 11. Cyanosis : 12. Pedal Oedema : 13. Lymphadenopathy : 14. Jugular venous pulsation :

:

:

:

:

:

:

:

#### SYSTEMIC EXAMINATION

Cardiovascular system	:
Respiratory system	:
Gastro-intestinal system	:
Central Nervous system	:
Urogenital system	:
Endocrine system	:

#### SIDDHA SYSTEM OF EXAMINATION

#### 1. THEGI (BODY CONSTITUTION):

- 1. Vatha udal
- 2. Pitha udal
- 3. Kaba udal
- 4. Thontha udal

#### 2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

- 1. Kurinji (Hilly terrain)
- 2. Mullai (Forest range)
- 3. Marutham (Plains)
- 4. Neithal (Coastal belt)
- 5. Paalai (Aridregion)

#### 3. KAALAM:

- 1. Kaar kaalam (Aavani-Purattasi)
- 2. Koothir kaalam (Ippasi-Kaarthigai)
- 3. Munpani kaalam (Maargazhi-Thai)4. Pinpani kaalam (Maasi-Panguni)
- 4. Pinpani kaalam (Maasi-Panguni)5. Ilavenil kaalam (Chithirai-Vaigasi)
- J. Havenin Kaalani (Cintiniai-Vaigasi
- 6. Muthuvenil kaalam (Aani-Aadi)

#### 4. GUNAM:

- 1. Sathuvam
- 2. Rasatham
- 3. Thamasam



#### 5. PORIPULANGAL (SENSORY ORGANS):

	Before treatment	After treatment
Mei (Skin)	Normal / Affected	Normal / Affected
Vai (Tongue)	Normal / Affected	Normal / Affected
Kann (Eye)	Normal / Affected	Normal / Affected
Mooku (Nose)	Normal / Affected	Normal / Affected
Sevi (Ear)	Normal / Affected	Normal / Affected

#### 6.KANMENDRIYAM (MOTOR ORGANS) :

	Before treatment	After treatment
Kai (Upper limb)	Normal /Affected	Normal /Affected
Kaal (Lower limb)	Normal /Affected	Normal /Affected
Vai (Oral cavity)	Normal /Affected	Normal /Affected
Eruvai (Anal region)	Normal /Affected	Normal /Affected
Karuvai (Uro- Genital region)	Normal /Affected	Normal /Affected

#### 7.KOSANGAL (SHEATH):

	Before treatment	After treatment
Annamaya kosam	Normal /Affected	Normal /Affected
Pranamaya kosam	Normal /Affected	Normal /Affected
Manomaya kosam	Normal /Affected	Normal /Affected
Vignanamaya kosam	Normal /Affected	Normal /Affected
Ananthamaya kosam	Normal /Affected	Normal /Affected

#### 8. SEVEN UDAL THAATHUKKAL (SEVEN SOMATIC COMPONENTS)

	Before treatment	After treatment
Saaram	Normal /Affected	Normal /Affected
Senneer	Normal /Affected	Normal /Affected
Oon	Normal /Affected	Normal /Affected
Kozhuppu	Normal /Affected	Normal /Affected
Enbu	Normal /Affected	Normal /Affected
Moolai	Normal /Affected	Normal /Affected
Sukkilam / Suronitham	Normal /Affected	Normal /Affected

# 9. UYIR THAATHUKKAL: [THREE HUMORS] (VALI/ AZHAL/ IYYAM)

# A) VALI

	0 <sup>th</sup> day	5 <sup>th</sup>	10 <sup>th</sup>	15 <sup>nd</sup>	20 <sup>th</sup>	25 <sup>th</sup>	<b>30</b> <sup>th</sup>	35day	40 th	45 th
	0 uay	day	day	day	day	day	day	JJuay	day	day
Praanan										
Abaanan										
Samaanan										
Udhaanan										
Viyaanan										
Naagan										
Koorman										
Kirukaran										
Devathathan										
Dhananjeyan										

### B) AZHAL

	0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> day	15 <sup>nd</sup> day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 th day	40 <sup>th</sup> day	45 th day
Analakam										
Ranjakam										
Saathakam										
Prasakam										
Aalosakam										

#### C) IYYAM

	0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> day	15 <sup>nd</sup> day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 <sup>th</sup> day	40 th day	45 th day
Avalambagam										
Kilethagam										
Pothagam										
Tharpagam										
Santhigam										

#### 10. ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

# I. NAADI: [PULSE PERCEPTION]

NAADI	0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> day	15 <sup>nd</sup> day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 <sup>th</sup> day	40 th day	45 th day

### II. SPARISAM: [PALPATION]

Day	SPARISAM
0 <sup>th</sup> day	
5 <sup>th</sup> day	
10 <sup>th</sup> day	
15 <sup>nd</sup> day	
20 <sup>th</sup> day	
25 <sup>th</sup> day	
30 <sup>rd</sup> day	
35 <sup>th</sup> day	
40th day	
45th day	

#### III. NAA: [TONGUE]

NAA	0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> d ay	15 <sup>nd</sup> day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 th day	40 <sup>th</sup> day	45 th day

#### **IV. NIRAM: [COMPLEXION]**

1. Vadham 2. Pitham

3. Kabam

#### V. MOZHI: [VOICE]

- High Pitched
   Low Pitched
- 3. Medium Pitched

#### VI.VIZHI: [EYES]

VIZHI	0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> day	15 <sup>nd</sup> day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 th day	40 <sup>th</sup> da y	45 th day

#### VII. MALAM: [BOWEL HABITS / STOOLS]

	Before treatment	After treatment
Niram		
Irugal		
Ilagal		
Others		

# VIII. MOOTHIRAM [URINE EXAMINATION]

#### NEERKKURI:

Neerkkuri	Before treatment	After treatment
Niram		
Manam		
Edai		
Nurai		
Enjal		

### **NEIKKURI:**

Neikkuri	Before treatment	After treatment
Aravana neendathu/		
Snake like pattern		
Azhipol paraviyathu		
Annular/Ring pattern		
Muththothu ninrathu		
Pearlbeadepattern		
Other patterns		

# CLINICAL ASSESSMENT

S.NO	CLINICAL	$0^{th}$	$5^{\text{th}}$	$10^{\text{th}}$	$15^{nd}$	20 <sup>th</sup>	25 <sup>th</sup>	30 <sup>rd</sup>	35 <sup>th</sup>	40 th	45 th
	SYMPTOMS	day	day	day	day	day	day	day	day	day	day
		-	-		-						-
1.	Arthritis of										
	more than 3										
	joints										
2.	Arthritis of										
	hand joints										
3.	Morning										
	stiffness > 1										
	hr										
4.	Symmetrical										
	arthritis										
5.	Restricted										
	movements										
6.	Spindled										
	appearance of										
	fingers										
7.	Anorexia										
8.	Low grade										
	fever										
9.	Subcutaneous										
۶.	nodules in										
	specific										
	places										
10.	Depression										
	Pression										

#### **CLINICAL EXAMINATION:**

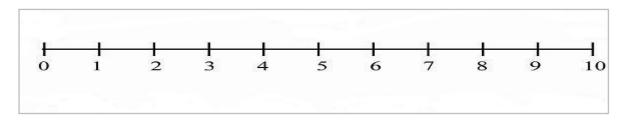
### **I.INSPECTION:**

S N O		0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> day	15 <sup>nd</sup> day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 <sup>th</sup> day	40 th day	45 th day
1	Muscle wasting of the upper limbs: Proximal- Distal	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent	Present/ Absent
2	Joint swelling: Major joints	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent	Present/ Absent
3	Joint swelling: Minor joints	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent	Present/ Absent
4	Skin over the joints:	Normal/ Reddish	Normal/ Reddish	Normal/ Reddish	Normal/ Reddish	Normal /Reddis h	Normal/ Reddish	Normal/ Reddish	Normal/ Reddish	Normal /Reddis h	Normal/ Reddish
5	Muscle wasting of the lower limbs:	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent	Present/ Absent
6	Nodules:	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent	Present/ Absent
7	Spindled appearanc e of fingers	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent	Present/ Absent
8	<b>Deformiti</b> eSwan neck deformity	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent
9	Button hole deformity	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent
1 0	Z shaped deformity	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent
1 1	Ulnar deviation of hand	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent
1 2	Ulnar deviation of foot	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent
1 3	Hallus valgus	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present /Absent

#### **II.PALPATION**

	0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> day	15th day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 <sup>th</sup> day	40 th day	45 th day
PAIN Onset:	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual	Sudden/ Gradual
Early morning Stiffness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Local heat	Mild/ Moderat e/ Severe	Mild/ Moderate/ Severe	Mild/ Moderate/ Severe	Mild/ Moderate/ Severe	Mild/ Moderate/ Severe	Mild/ Moderate / Severe	Mild/ Moderate/ Severe	Mild/ Moderate/ Severe	Mild/ Moderate / Severe	Mild/ Moderat e/ Severe
Stiffness	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Tendern ess	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Restricti on	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No	Fully/ Partial/ No

#### UNIVERSAL PAIN ASSESMENT SCALE:



- 0 : No Pain
- 1-3 : Mild pain
- 4-6 : Moderate pain
- 7-10: Severe pain

#### **RESTRICTED MOVEMENT ASSESSMENT SCALE:**

#### **GRADATION OF MOVEMENTS**

Grade 1 – Able to perform normal duties

Grade II – Moderate Restriction – Self care is possible

Grade III - Marked restriction - Limited self care/some assistance required.

Grade IV - Confined to bed or wheel chair

#### AUTONOMIC NERVOUS SYSTEM

	0 <sup>th</sup> day	5 <sup>th</sup> day	10 <sup>th</sup> day	15 <sup>nd</sup> day	20 <sup>th</sup> day	25 <sup>th</sup> day	30 <sup>rd</sup> day	35 <sup>th</sup> day	40 th day	45 th day
Bladder										
Bowel										

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

#### NATIONAL INSTITUTE OF SIDDHA AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF MARUTHUVAM

An open Clinical study on "Merugulli thylam (Internal Medicine)" in the treatment of "Vali Azhal Keel Vayu" (Rheumatoid Arthritis).

#### Principal Investigator: Dr.M.Suganthi 1. SERIAL NO:

3. NAME:

#### 2. OP /IP NO: 4. AGE/GENDER:

<b>BLOOD INVESTIGATIONS</b>			NORI VAL	UES	BEFORE TMT (WITH DATE)	AFTER TMT (WITH DATE)
HB( gm/dl)			M:12 W:11			
T.WBC (cells/cu.mm)			400 110	-		
	Polymo	orphs	40-	75		
	Lymph	ocytes	20-	40		
DIFFERENTIAL	Monoc	-	2-1	0		
COUNT (%)	Eosino	phils	1-	6		
	Basoph		0-	1		
T.RBC(million cells/cu.)	mm)		M:4.0 W:3.			
ESR(mm/hour)	<sup>1</sup> / <sub>2</sub> hr.		M:6- W:7-			
	1 hr.					
Blood Investigations		Nor Val			Before AT(WITH DATE)	After TMT (WITH DATE)
HCT/PCV		Men:36- 51% Women:35- 48%				

### FORM-III - LABORATORY INVESTIGATIONS

		r	
MCV		Men :78- 98%ft Women : 78-98%ft	
r	МСН		
МСНС		Men : 31- 37 gms/dl Women : 31-37 gms/dl	
Platelet count		Men : 1.5 – 4.5 lkhs/µl Women : 1.5-4.5 lkhs/µl	
Bleeding Time		1-3 minutes	
Clott	ting Time	3-8 minutes	
Blood	Fasting	70-110	
glucose	PP	80-140	
(mg/dl)	Random	80-120	
	Blood urea	16-50	
RFT (mg/dl)	Serum creatinine	0.6-1.2	
	Total bilirubin	0.2-1.2	
	Direct bilirubin	0.1-1.2	
	Indirect bilirubin	0.2-0.7	
LFT (mg/dl)	SGOT	0-40	
Li i (ing/ui)	SGPT	0-35	
	Alkaline phosphatase	80-290	

	BLOOD INVESTIGATI ONS	NORMAL VALUES	BEFORE TMT	AFTER TMT
	Serum calcium	8.5-10.5		
OTHER TESTS.	Serum phosphorus	3.0-4.5		
	Serum uric acid	<b>Men:3.0-9.0</b> Wo <b>men:2.5-7.5</b>		
	Serum protein	6.0-8.0		
	Serum albumin	3.5-5.0		
	Serum globulin	2.3-3.5		

Special	Before TMT(with	After TMT (With
investigations	Date)	Date)
RA FACTOR		
ASO TITER		
CRP		
X – RAY		
FINDINGS		

Urine investigation	Before TMT(with Date)	After TMT (With Date)
Neer kuri		
Niram		
Edai		
Manam		
Nurai		
Enjal		
Nei kuri		
Albumin		
Fasting sugar		
PP sugar		
Deposits		

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

#### NATIONAL INSTITUTE OF SIDDHA

#### AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

#### DEPARTMENT OF MARUTHUVAM

#### An open Clinical study on "Merugulli thylam (Internal Medicine)" in the treatment of "Vali Azhal Keel Vayu" (Rheumatoid Arthritis).

#### Principal Investigator: Dr.M.Suganthi

#### FORM -IV- DRUG COMPLIANCE FORM

#### SERIAL NO:

#### NAME:

#### **DRUG NAME:**

On 1 <sup>st</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 5 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 10 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 15 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 20t <sup>h</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 25 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 30 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 35 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 40 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)
On 45 <sup>th</sup> day-Date:	Drugs issued:	(Gms)	Drugs returned:	(Gms)

Day	Date	Morning	Evening	Day	Date	Morning	Evening
Day 1				Day25			
Day2				Day26			
Day3				Day27			
Day4				Day28			
Day5				Day29			
Day6				Day30			
Day7				Day31			
Day8				Day32			
Day9				Day33			
Day10				Day34			
Day11				Day35			
Day12				Day36			
Day13				Day37			
Day14				Day38			
Day15				Day39			
Day16				Day40			
Day17				Day41			
Day18				Day42			
Day19				Day43			
Day20				Day44			
Day21				Day45			
Day22							
Day23							
Day24							

Date: Station: Signature of the Investigator: Signature of the Lecturer:

Signature of the HOD

# NATIONAL INSTITUTE OF SIDDHA AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

#### DEPARTMENT OF MARUTHUVAM

# An Open Clinical study on "MERUGULLI THYLAM (Internal Medicine)" in the treatment of "Vali Azhal Keel Vayu" (Rheumatoid Arthritis) FORM V– PATIENT INFORMATION SHEET

Name of Principal Investigator: Dr.M.Suganthi,

# INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, Dr.M.Suganthi, studying M.D (Siddha) I st year at National Institute of Siddha, Tambaram Sanatorium doing a clinical trial on "Vali Azhal Keel Vayu" (Rheumatoid arthritis). It is a Auto immune disease, occurring throughout the world. In this regard, I am in a need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine "**MERUGULLI THYLAM**" (Internal medicine) 9 gram(9 ml)-Morning only,(Drug administration-3 days.,drug holiday-2 days) for 45 days . If you wish to stay in the In Patient ward, the internal medicine will be provided to you assuring that you will not be definitely hurt in any course of treatment.

The information I am collecting in this study will remain between you and the principal investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. Ur name won't be mentioned in the lab investigation form instead a code will be used.

The questionnaire will take approximately 20 minutes of your time.

If you want to know more about this study before taking part, you can ask me all the questions you want or contact Dr.M.Suganthi, PG Scholar cum principal investigator of this study, National Institute of Siddha, Chennai-47. You can also contact the Membersecretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel.No: 91-44-22380789, for rights and participation in the study.

#### தகவல் படிவம்.

#### தேசிய சித்த மருத்துவ நிறுவனம்,

#### அயோத்திதாஸ் பண்டிதர் மருத்துவமனை சென்னை 47

வளி அழல் கீல்வாயு என்னும் நோய்க்கான மெருகுள்ளி தைலம் (உள் மருந்து) சித்த மருந்துகளின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம். முதன்மை ஆராய்ச்சியாளர் பெயர்: மருத்துவர் ம.சுகந்தி

**நிறுவனத்தின் பெயர்** : தேசிய சித்த மருத்துவ நிறுவனம்,

தாம்பரம் சானட்டோரியம்

சென்னை 47

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர். ம.சுகந்தி), **வளி அழல் கீல்வாயு** என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

வளி அழல் கீல்வாயு என்னும் என்னும் நோயில் சிறு, பெரு மூட்டுகளில் வலி, வீக்கத்தை உண்டாக்கி காலையில் விறைப்பு தன்மையை உண்டாக்கும்

இது பரவ கூடிய நோய் அல்ல.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகள் கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன்.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதிஅளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப்படமாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க சிகிச்சை அளிக்கப்படும்.

இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக மெருகுள்ளி தைலம் 9கி(9மி.லி), 1 வேளை (காலை மட்டும்) உணவுக்கு முன் 45 நாட்கள் உட்கொள்ள வேண்டும். 3 நாட்களுக்கு தொடர்ந்து மருந்து உண்டு பின் 2 நாட்களுக்கு மருந்து உண்ணாமல் பத்தியம் மட்டும் காக்க வேண்டும். வெளி நோயாளர்கள் 5 நாட்களுக்கு ஒருமுறை மருத்துவமனைக்கு வரவேண்டும். உள் நோயாளியாக தங்க விருப்பம் தெரிவிக்கும் பட்சத்தில் நோய்க்கு சிகிச்சை அளிக்கப்படும்.

இந்த ஆராய்ச்சியில் நோயினராக சேர்ந்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் விலகி கொள்ளலாம்.

இந்த ஆராய்ச்சி சம்பந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மை பற்றியும் முதன்மை ஆராய்ச்சியாளரான மருத்துவர் ம.சுகந்தி(பட்ட மேற்படிப்பாளர் பொதுமருத்துவ துறை) அணுகவும். கைப்பேசி எண் 8056786753

மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறப்பட்டுள்ளது

இந்த மருந்து சிறப்பாக **வளி அழல் கீல்வாயு** நோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது.

ஏற்கனவே உபயோகத்தில் உள்ளது போன்ற மருந்து நோயாளிகளிடம் எந்த வித பக்க விளைவுகளையும் ஏற்படுத்தவில்லை.

மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்தப்படுகிறது

#### NATIONAL INSTITUTE OF SIDDHA

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Principal Investigator: Dr.M.Suganthi

#### FORM-VI – CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

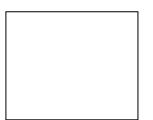
Signature of the participant

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm individual has given consent freely."

Date:

Signature of a witness (Selected by the participant bearing no connection with the survey team)



Left thumb Impression of the Participant

#### FORM – VI <u>ஒப்புதல் படிவம்</u>

#### ஆய்வாளரால் சான்றளிக்கப்பட்டது

#### தேசிய சித்த மருத்துவ நிறுவனம், அயோத்திதாஸ் பண்டிதர் மருத்துவமனை, சென்னை.

#### வளி அழல் கீல்வாயு என்னும் நோய்க்கான மெருகுள்ளி தைலம் (உள் மருந்து) சித்த மருந்துகளின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம். தகவல் படிவம்.

#### <u>ஒப்புதல் படிவம்-ஆய்வாளரால் சான்றளிக்கப்பட்டது</u>

நான் இந்த ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி : கையொப்பம்:

இடம்:

பெயர்

:

#### நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது நான் இந்த வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையைத் தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாகத் தோவு செய்யும் உரிமையைக் கொண்டு அழல் **கீல்வாயு** நோய்க்கான **மெருகுள்ளி தைலம்** (உள் மருந்து) மருந்தின் பரிகரிப்புத் ഖണി திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி:	கையொப்பம்:
-------	------------

இடம்: பெயர் :

தேதி:	சாட்சிக்காரா் கையொப்பம்:

இடம்:

பெயர்:

உறவுமுறை:

விரிவுரையாளா் கையொப்பம்:

துறைத்தலைவர் கையொப்பம்:

#### NATIONAL INSTITUTE OF SIDDHA,

#### CHENNAI – 47

# AYOTHIDASA PANDITHAR HOSPITAL DEPARTMENT OF MARUTHUVAM An Open Clinical study on "Merugulli thylam (Internal Medicine)" in the treatment of "Vali Azhal keel Vayu" (Rheumatoid Arthritis)

# FORM VII- WITHDRAWAL FORM/ADVERSE DRUG REACTION/PHARMACOVIGILANCE FORM

# **IEC NO: NIS/IEC**

AGE:		
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**SERIAL NO:** 

#### DATE OF TRIAL COMMENCEMENT:

#### DATE OF WITHDRAWAL FROM TRIAL:

#### **REASONS FOR WITHDRAWAL:**

• Long absence at reporting :	Yes/ No
• Irregular treatment:	Yes/ No
• Shift of locality :	Yes/No
• Increase in severity of symptoms:	Yes/No
• Development of severe adverse drug reactions:	Yes/No

# NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

# Reporting Form for Suspected Adverse Reactions to Siddha Drugs

**Please note:** i. All consumers / patients and reporters information will remain confidential.

ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code:

State:

# **1.** Patient / consumer identification (please complete or tick boxes below as appropriate)

Name	Father name	Patient / Record No.
Ethnicity	Occupation	
Address		Date of Birth / Age:
Village / Town		
Post / Via		Sex: Male / Female
District / State		Weight :
		Degam:

### 2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation	Season:
Description of reaction	Geographical area:

# **3.** List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:

Medicine	Daily	Route of	Date		Diagnosis for
	dose	administration	Starting	Stopped	which medicine
		& Vehicle – Adjuvant			taken
0:11		Aujuvant			
Siddha					
Any other					
system of					
medicines					

### 4. Brief details of the Siddha Medicine which seems to be toxic :

Details	Drug – 1	Drug – 2	Drug - 3
a) Name of the medicine			
b) Manufacturing unit and			
batch No. and date			
c) Expiry date			
d) Purchased and obtained			
from			
e) Composition of the			
formulation / Part of the drug			
used			

b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

#### 5. Treatment provided for adverse reaction:

# 6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)

Recovered:	Not	Unknown:	Fatal:	If Fatal
	recovered:			Date of death:
Severe: Yes / No	. Reaction	Reaction abated after drug stopped or dose reduced:		or dose reduced:
Reaction reappeared after re introduction:		iction:		

Was the patient admitted to hospital? If	
yes, give name and address of hospital	

#### 7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:

#### 8. Whether the patient is suffering with any chronic disorders?

Hepatic	Renal	Cardiac	Diabetes	Malnutrition
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Any Others

#### 9. H/O previous allergies / Drug reactions:

#### 10. Other illness (please describe):

#### 11. Identification of the reporter:

**Type** (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer /

Distributor / Supplier / Any others (please specify)

Name:

Address:

Telephone / E – mail if any :

#### Signature of the reporter:

Date:

#### Please send the completed form to:

Name & address of the RRC-ASU / PPC-ASU The Director

National Institute of Siddha,

(Pharmacovigilance Regional Centre For Siddha

Tambaram Sanatorium, Chennai-600 047.

<sup>∞</sup> (O) 044-22381314 Fax : 044 – 22381314

Website : www.nischennai.org

Email : <u>nischennaisiddha@yahoo.co.in</u>

### This filled-in ADR report may be sent within one month of observation /occurrence of ADR

Who Can Report?	
What to Report?	⇒ Any Health care professionals like Siddha Doctors / Nurses / Siddha Pharmacists / Patients etc.
Confidentiality	$\Rightarrow$ All reactions, Drug interactions,
	<ul> <li>⇒ The patient's identity will be held in strict confidence and protected to the fullest extent.</li> <li>⇒ Submission of report will be taken up for remedial measures only not for legal claim</li> </ul>

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

#### NATIONAL INSTITUTE OF SIDDHA AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

#### DEPARTMENT OF MARUTHUVAM

# An open Clinical study on "Merugulli thylam(Internal Medicine)" in the treatment of "Vali Azhal Keel vayu" (Rheumatoid Arthritis).

#### Principal Investigator: Dr.M.Suganthi

#### சேர்க்க கூடிய உணவுகள்:

#### காய்கள்:

முருங்கைபிஞ்சு,

அவரைபிஞ்சு,

பிரண்டை,

காரட்,

பீட்ரூட்.

#### கீரைகள்:

கரிசாலை,

பொன்னாங்கண்ணி,

மணத்தக்காளி,

முருங்கைகீரை,

பசலைகீரை,

சிறுகீரை,

கறிவேப்பிலை,

கொத்தமல்லி.

புதினா.

#### பழங்கள்:

மாதுளை, ஆப்பிள், வாழை, பேரீச்சை, அத்தி, திராட்சை, கொய்யா நாவல், சப்போட்டா,

உலர் திராட்சை.

#### தானியங்கள்

முளை கட்டிய பயிர் வகைகள்,

சோயாபீன்ஸ்,

உளுந்து,

வெந்தயம்.

#### அசைவம்:

வெள்ளாட்டுகறி ஈரல்,

எலும்புமஜ்ஜை,

#### மற்றவை:

பனை வெல்லம்

பால்

#### தவிர்க்க வேண்டியவைகள்:

உப்பு கோழிக்கறி, மீன், நண்டு, கருவாடு, வேர்க்கடலை, எள், தேங்காய், பலா, புளிப்பு பொருள்கள், புளிப்பு தயிர் மோர், ஊறுகாய், பெண்போகம், புகையிலை , வெற்றிலை,பாக்கு.



# The Tamil Padu Br.M.G.R. Medical University 69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....SugANTHI: M.

For participating as Resource Person / Delegate in the Twenty First Workshop on

# **"RESEARCH METHODOLOGY & BIOSTATISTICS"**

For AYUSH Post Graduates & Researchers

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 25th to 29th April 2016.



Prof. Dr. P.ARUMUGAM, M.D.,

**REGISTRAR** i/c

Prof. Dr.S.GEETHALAKSHMI, M.D., Ph.D. VICE CHANCELLOR

Chelin



#### NATIONAL INSTITUTE OF SIDDHA, CHENNAI - 600047

#### BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation "Merugulli thylam" (Internal) taken up for Post Graduation Dissertation studies by **Dr.M.Suganthi** M.D.(S), II year, Department of Maruthuvam, 2017, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

*Alocasia indica* (Roxb.) Schott (Araceae), Root tuber *Allium sativum* Linn. (Liliaceae), Bulb *Ricinus communis* Linn. (Euphorbiaceae), Seed oil



Date: 25-07-17

Authorized Signatory Dr. D. ARAVIND, M.D.(s),M.Sc., Assistant Professor Department of Medicinal Botany National Institute of Siddha Chennal - 600 047, INDIA

#### NATIONAL INSTITUTE OF SIDDHA- राष्ट्रीय सिद्ध संसथान Ministry of AYUSH- आयुष मंत्रालय GOVERNMENT OF INDIA-भारत सरकार TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियमचेन्नई -600 047 फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314 ईमेल: <u>nischennaisiddha@yahoo.co.in</u> येब :<u>www.nischennai.org</u>

F.No.NIS/6-20/IEC/15-16

Dt: 14.10.2016

#### CERTIFICATE

Addroop of Ethiop Committee, Nation					
Address of Ethics Committee: National Institute of Siddha, Tambaram					
Sanatorium, Chennai-600047, Tamil Nadu, India					
Principal Investigatory Dr. M. Sugarthi	Lucas Deut of March				
Principal Investigator: Dr. M.Suganthi – I year, Dept.of Maruthuvam					
Protocol Title: - An open clinical trial on "Merugulli Thylam" (Internal Medicine) in the					
treatment of "Vali Azhal Keelvayu" (Rheumatoid Arthritis)					
Documents filed	1) Protocol, 2) Data Collection forms				
Clinical trial Ductors I					
Clinical trial Protocol	Yes-(M.D-Dissertation)				
(others – Specify)					
Informed consent documents	N/				
mormed consent documents	Yes				
Any other documents					
Any other documents	-				
Date of IEC approval & its number	NIS/IEC/2016/11-07/ 14.10.2016				

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

S. gisgansussa

(Dr.V.Subramanian) Chairman



(Prof.Dr.V.Banumathi)

(Prof.Dr.V.Banumathi) Member Secretary



#### Clinical Trial Details (PDF Generation Date :- Thu, 05 Jul 2018 16:01:18 GMT)

CTRI Number		tered on: 06/03/2018] - Trial Registered Retrospectively					
Last Modified On	19/04/2018						
Post Graduate Thesis		Yes					
Type of Trial	Observational						
Type of Study	M D Dissertation						
Study Design	Single Arm Trial						
Public Title of Study	An open clinical trail on "MERUGULLI THYLAM"(Internal medicine) in the treatment of Mudakkuvatham.						
Scientific Title of Study	An open clinical trail on "MERUGULLI THYLAM" (Internal medicine) in the treatment of "VALI AZHAL KEELVAYU" (Rheumatoid Arthritis).						
Secondary IDs if Any	Secondary ID	Identifier					
	nil	NIL					
Details of Principal		Details of Principal Investigator					
Investigator or overall	Name	DR M Suganthi					
Trial Coordinator	Designation	PG scholar					
(multi-center study)	Affiliation	National Institute of siddha					
	Address	Pepartment of Maruthuvam,National Institute of Siddha, Ayodidoss andithar hospital Tambaram Sanatorium,Chennai Cancheepuram AMIL NADU 00047 ndia					
	Phone	8056786753					
	Fax						
	Email	drsuganthi6@yahoo.com					
Details Contact	Details Contact Person (Scientific Query)						
Person (Scientific	Name	DR K Manikavasagam					
Query)	Designation	Professor					
	Affiliation	National Institute of Siddha Tambaram Sanatorium Chennai 47					
	Address	Department of Maruthuvam,National Institute of Siddha, Ayodido pandithar hospital Tambaram Sanatorium,Chennai Kancheepuram TAMIL NADU 600047 India					
	Phone	9444249798					
	Fax						
	Email	dr.kmvm@gmail.com					
Details Contact Person (Public Query)	Details Contact Person (Public Query)						
reison (rubiic Query)	Name	DR H Vedha merlin kumari					
	Designation	Lecturer					
	Affiliation	National Institute of siddha					
	Address	Department of Maruthuvam,National Institute of Siddha, Ayodidoss pandithar hospital Tambaram Sanatorium,Chennai Kancheepuram TAMIL NADU 600047 India					



	Phone		989	94782366				
	Fax							
	Email		dr.v	vetha@gmail.co	m			
Source of Monetary or	Source of Monetary or Material Support							
Material Support	<ul> <li>National Institute of Siddha, Ayodidoss pandithar hospital Tambaram Sanatorium, Chennai</li> </ul>					natorium,Chennai		
Primary Sponsor	Primary Sponsor Details							
	Name		Nat	tional Institute of				
	Address National Institute of			Siddha Tambara	am Sana	torium Chennai 47		
	Type of Sponsor Research institution			n and hospital				
Details of Secondary	Name	Name			Address			
Sponsor	NIL				NIL			
Countries of	List of Countries							
Recruitment	India							
Sites of Study	Name of Principal Investigator	Nam	e o	f Site	Site Address		Phone/Fax/Email	
	DR M Suganthi	Ayothidoss pandithar hospital		oss pandithar	Room no 1 Department of Maruthuvam National institute of siddha Tambaram Sanatorium Chennai 47 Kancheepuram TAMIL NADU		8056786753	
							drsuganthi6@yahoo.co m	
Details of Ethics Committee	Name of Committee	nittee Approval Status		Date of Approval		Is Independent Ethics Committee?		
	The Institutional Ethics Committee	Approved		d	14/10/2016		No	
Regulatory Clearance	Status	Status			Date			
Status from DCGI	Not Applicable				No Date Specified			
Health Condition /	Health Type				Condition			
Problems Studied	Patients				Arthritis involving three or more joints,Symmetrical joint involvement Morning stiffness swelling of small joints of hand and foot			
Intervention /	Туре	Type Name			Details			
Comparator Agent	Intervention		Merugulli thylam				g only (2 days drug	
Inclusion Criteria	Inclusion Criteria							
	Age From 20.00 Year(s)							
	Age To 60.00 Year(s)							
	Gender	Both         Age:20-60 years         Sex:Both male and female         Symmetrical joint involvement         Arthritis of three or more joints         Rheumatoid factor positive or negative         Morning stiffness         Deformities like Swan neck deformity and Button hole deformity         Swelling especially in the inter-phalangeal joint						
	Details							
	Patients willing for admission in IPD or willing to a Patient willing to undergo Radiological investigation laboratory investigation							



		Patients willing to sign the informed consent stating that he/she will consciously stick to the treatment during 45 days but can opt out of the trial of his/her own conscious discretion.				
<b>Exclusion Criteria</b>	Exclusion Criteria					
	Details	Pregnancy and lactation Tubercular arthritis Any other serious systemic illness like cancer, cardiac disease Osteoarthritis Psoriatic arthritis Gouty arthritis Diabetic mellitus Hypertension Thyroidism(Hypo/hyper)				
Method of Generating Random Sequence	Not Applicable					
Method of Concealment	Not Applicable					
Blinding/Masking	Not Applicable					
Primary Outcome	Outcome		Timepoints			
	Assessment of pain is by Univ assessment scale.Other clinic symptoms will be assessed b methods	cal signs and	before and After treatment (45 days) Assessment of pain is by Universal pain assessment scale.Other clinical signs and symptoms will be assessed by Gradation methods			
Secondary Outcome	Outcome		Timepoints			
	Laboratory investigations suc factor,CRP,ASO titre will also of the study		Before and after treatment(45 days)			
Target Sample Size	Total Sample Size=40       Sample Size from India=40					
Phase of Trial	N/A					
Date of First Enrollment (India)	01/11/2017					
Date of First Enrollment (Global)	No Date Specified					
Estimated Duration of Trial	Years=1 Months=0 Days=0					
Recruitment Status of Trial (Global)	Not Applicable					
Recruitment Status of Trial (India)	Open to Recruitment					
Publication Details	nil					
Brief Summary	Its is a single non randomized open label trial to determine the efficacy and safety of "MERUGULLI THYLAM" (Herbal formulation) in the patients with VALI AZHAL KEELVAYU (Rheumatoid arthritis) in this trial 40 patients will be recruited and the trial drug will be administered kaal balam-9gram (9 ml)-3 days morning only (2 days drug holiday) for a period of 45 days, During the trial period if any AE/SAF/SUSAR will be noticed and referred to pharmacovigilance department in NIS and further management will also be given in NIS OPD/IPD. The entire trial will be monitored by the research monitoring committee of NIS. During this trial all the safety efficacy parameters will be recorded in the CRF after completion of the trial all the safety related data will be analysed statistically, the outcome of this trial will be published in Indian Journal of Medical Research.					

INTRODUCTION

# DISCUSSION

# SUMMARY

## CONCLUSION

# BIO-CHEMICAL ANALYSIS

# BIBLIOGRAPHY

# AIM AND OBJECTIVES

# REVIEW OF LITERATURE

MATERIALS AND METHODS (PROTOCOL) OBSERVATION AND RESULTS

LABORATORY INVESTIGATIONS ANNEXURE

# CERTIFICATES

# SIDDHA ASPECT

 $\mathcal{M}\mathcal{O}\mathcal{D}\mathcal{E}\mathcal{R}\mathcal{N}\,\mathcal{A}\mathcal{S}\mathcal{P}\mathcal{E}\mathcal{C}\mathcal{T}$ 

# PREPARATION AND PROPERTIES OF DRUG

STANDARDIZATION REPORT