Comparative clinical study of **"*Kandathiri Chooranam*"** (Internal Medicine) and **"*Erandai Thailam*" (**External Medicine**)** in the treatment of *"**Azhal Keel Vayu**"* (Osteoarthritis of Knee Joint) with and without *Varmam* therapy.

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled Comparative clinical study of ***"Kandathiri chooranam"*** (Interanl medicine) and ***"Erandai Thylam"*** (External medicine) in the treatment of ***Azhal Keelvayu*** **(Osteoarthritis of Knee Joint)** with and without ***varmam therapy*** is a bonafide and genuine research work carried out by me under the guidance of **Prof**. **Dr .N. J. MuthuKumar MD(S). PhD, HOD**, Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date: **Signature of the Candidate**
Dr.V.Rubini

Place: Chennai-47

BONAFIDE CERTIFICATE

Certified that I have gone through the dissertation submitted by, **Dr.V.Rubini, (Reg.No: 321613208)** a student of final year M.D(s), Branch III- Sirappu Maruthuvam, National Institute of Siddha,Chennai-47, and the dissertation work has been carried out by the individual only. This dissertation does not represent or reproduce the dissertation submitted and approved earlier.

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INTRODUCTION

The Siddha system of medicine mainly practiced in the Southern part of India is one of the earliest traditional medicine systems in the world and deals with physical, psychological, social and spiritual well being of an individual. Siddha system of medicine is the most primitive medical system. It doesn't consider treatment and prevention separately. The main aim of this system is prevention of disease.

As per Siddha system the man kind is inseparable from the universe.

"அண்டத்திலுள்ளதே பிண்டம்
பிண்டத்திலுள்ளதே அண்டம்"

Siddhars explained the body as a whole is made up of five elements Earth, water, fire, air, and Ether which are the foundamentals of creation, protection, and destruction. The diagnosis of disease in Siddha system of medicine relies on the Eight way examination methods (*Envagai thervu*), *Naadi, Sparisam, Niram, Mozhi, Vizhi, Malam, Moothiram,* which are evaluated in terms of the three humors. The drugs for treating disease have been procured from the plants, animal, and mineral origin. Various type of medicinal preparations such as gruels, powder, decoctions, medicated ghee, oil, thailam, paste etc, are given vively. Such prepared drugs have the properties and qualities pertaining to *panchabhootham.*

The human body is conditioned by three humors consisting of *Vatham, Pitham, Kabam*. These three vital forces (*Vaatham, Pitham, Kabam*) of cosmic elements are named under the action or reaction of the panchaboothams.The deranging of this vital force causes disease. Aim of this system of medicine is to balance the vital forces and setting the right the equilibrium of the three energies.

மிகினும் குறையினும் நோய் செய்யும் நுலோர்
வளிமுதலா எண்ணிய மூன்று

In the Siddha classic *Siddha Maruthuvam Pothu,* ***Azhal keel vaayu*** is described as one amon 10 types of *Keel vayu* with reference in *Sababathi kaiyaedu* , among 10 types of *Keel vayu. Azhal keel vaayu* is defined as a condition with symptoms of pain,

swelling, and stiffness in the knee joint, decrease in mobility of the knee, creaking, crackly sound that is heard when the knee moves, and it may be correlated to symptoms of Osteoarthritis in modern science. Various Siddha formulation has been mention in Siddha literature to treat Osteoarthritis.

Osteoarthritis is a joint inflammation that results from cartilage degeneration. OA can be caused by aging, heredity, and injury from trauma or disease. The most common symptoms of pin, swollen joints, stiffness, joint creaking, loss of range of movements.

Osteoarthritis is the most common form of arthritis, affecting about 237 million people. Among those over 60 years old, about 10% of males and 18% of females are affected. It becomes more common in both sexes as people become older.

Patients diagnosed with Osteoarthritis visiting Ayothidoss Pandithar Hospital considerably increasing for the past few years. There are many treatment modalities available in modern system especially with Non steroidal anti-inflammatory (NSAID) drugs, steroids to treat ***Azhal keelvayu*** . Due to more adverse effects of these drugs the patients were suffering more than cure . So author decided to find a new formulation for this ailment.

I investigator had selected ***"Kandathri Chooranam"*** (Internal) and ***"Erandai thylam"*** (External) for treating ***Azhal keelvayu*** (Osteoarthritis), Which is a poly herbal preparation to equalize the de-ranged *Vaatham*, *Pitham* and *Kabam*. The ingredient of the trail drug , *Cuminum cyminum*, *Abies spectabilis*, *Syzygium aromaticum*, *Embelia ribes* possess Anti - inflammatory, Anti – oxidant property, Aanalgesic property. Hence this trail drug has been selected for treating *Azhal Keel Vayu* (Osteoarthritis).

AIM AND OBJECTIVE

To evaluate the therapeutic efficacy of Siddha herbal formulation of ***"Kandathiri chooranam"*** (Internal) and ***"Erandai Thailam"*** **(**External) for ***"Azhal KeelVayu"*** (OsteoArthritis of Knee joint) with and without ***Varmam*****.**

OBJECTIVE:

PRIMARY OBJECTIVE:

To evaluate the therapeutic efficacy of Siddha drugs ***"Kandathiri Chooranam"***(Internal) and ***"Erandai Thailam"*** (*E*xternal) in reducing the pain and restricted joint movements in the treatment of ***"Azhal Keel Vayu"*** (Osteoarthritis) through comparative clinical study.

SECONDARY OBJECTIVE:

1.To study the Siddha basic principles like *Envagai thervu, Kaalam, Udal Thaathu* etc.
2.To Study the effect of *Varmam* in *Azhal Keel Vayu* patients along with trail drug.

REVIEW OF LITERATURE

SIDDHA ASPECT OF *AZHAL KEEL VAYU*

Siddha system of Medicine is an ancient one enriched with good resources. The sources of Siddha medicines include Herbs, Minerals, Metals and also animal origin.

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

The universe around as in the Macrocosm *(Andam*) and the human body is considered as the Microcosm (*Pindam*). Any changes in the Macrocosm will have its impact in the Microcosm in the human body.

"நிலந்தீ நீர்வளி விசும்போடைந்தும்
கலந்த மயக்கம் உலகம் ஆதலின்
இருதினை ஐம்பால் இயனெறி வழா அமைத்
திரிவில் சொல்லொடு தழாஅல் வேண்டும்."

தொல்காப்பியம் பொருள் அகராதி.

The poet explains that both Andam and Pindam formed by the basic five elements called p*anchaboodhams*. They are

1. *Pirithivi* (Earth)
2. *Appu* (Water)
3. *Theyu* (Fire
4. *Vaayu* (Air)
5. *Aahayam* (Ether)

These five elements combined to form Three *Thathus*.

1. *Vaatham*
2. *Pitham*
3. *Kabam*

"தலங்காட்டி இந்தச் சடமான வைம்பூதம்
நிலங்காட்டி நீர்காட்டி நின்றிடுந் தீ காட்டி
வலங்காட்டி வாயுவால் வளர்தே இருந்த
குலங்காட்டி வானிற் குடியா யிருந்ததே"
"இருந்திடு மிவ்வைந்த் லெடுத்த சடமிது"

(திருமூல்ர் நாடி)

These three *thathu* composed of

1. *Vatham* = Air + Ether
2. *Pitham* = Fire
3. *Kabam* = Earth + water

The physiological units of the Human body is otherwise called as *Vali* (*Vatham), Azhal (Pitham), Iyyam (Kabam).* They are also formed by the combination of the five basic elements. Accordingly *Vali* is formed by the combination of *Vayu* (Air) and *Aagayam* (Space). This is the Creative force. *Azhal* is formed by *theyu* (Fire). This is the Force of Preservation. *Iyyam* is formed by *Prithivi* (Earth) and *Appu* (Water). This is the Force of Protection. These three humors are in the ratio of 4:2:1 in equilibrium which is a healthy normal condition and disturbance in their equilibrium leads to diseases. This is denoted in

"பொங்கியீரைந்துக்குட் பொல்லா மூன்று தான்
தங்கியவாயுச் சமர்த்தன் மகாவதம்
பங்கியவன்னியார் பகுந்தது பித்தமே"
"பகுந்த சலத்திற் பரிசிக்கும் நல்கலையம்
வகுந்தஇம் மூன்றால் வளர்தது நோயெல்லம்"

(பதிணென் சித்தர் நாடி சாத்திரம்)

These three *thathus* perceived as *Naadi* which is unique feature of Siddha system.When the above three humours are affected (or) not in a balanced state , they become Kuttram which predisposes to diseases.

I.Vali (Vaatham)

These active elements are always supported by the two stable elements, for change can only happen upon the foundation of stable. Thus *Vayu* and *Aahaayam* combine to become "*Vaatham* humor" which controls all aspects of movements as well as space with in the body. In spite of this combination, however, *Vaatham* sends to primarily display the characteristics of Vayu-Air. The words "Dry, light, cold, quick, rough, minute and mobile" describes the characteristics of *Vaatham.*

II.Azhal (Pitham)

This is the function that governs all the body's conversion processes as well as its heat and energy producing capacities. *Pitham* is primarily characterized by the qualities of *Theyu*, which are " hot, sharp, penetrating, light, acidic, and slightly oily ".

III. Iyyam(Kabam):

It controls liquefaction, lubrication and cohesion. It is also responsible for giving solidity and structure to the body. *Kabam* primarily reflects the qualities of the water, but also some traits of the earth elements, consequently, *Kabam* is heavy, slow, cold, steady, solid and oily.

ARTHRITIS – *KEEL VAYU*

Arthritis is a group of conditions involving damage to the joint of the body. There are over 100 different forms of arthritis. Excess of *vaatham* affects the joints all over the body and Vitiation of *Kabam* causes indigestion. Thus the end product of digestion associated with *vaatham, pitham, kabam* blocks the tissue pores and passages with waxy material. It also affects simultaneously the joints of the body such as knee, shoulder, hip, neck etc. This produces the pain, swellon of the joints. Hence it is also known as ***"AZHAL KEEL VAYU".***

AZHAL KEEL VAYU :

In Siddha literature *Azhal keel vayu* described under *keel vayu* . Then the *keel vayu* is the general term that includes all kind of joint disorders.

Azhal keel vaayu is defined as increase in *vaatham* and *pithakutram,* characterised by pain in joints, swelling, tenderness, caused by various causes as mentioned below.

TYPES OF *KEEL VAYU*

There are ten types of *KeelVayu* which are mentioned in the text *"Siddha Maruthuvam Pothu". Azhal Keelvayu* is one among 10 types of *Keel Vayu.*

The 10 types are mentioned below

1.*Vali Keel Vayu*

2.Azhal Keel Vayu

3.IyyaKeel Vayu

4.Vali Azhal Keel Vayu

5.Vali Iyya Keel Vayu

6.Azhal Vali Keel Vayu

7.Azhal Iyya Keel Vayu

8.Iyya Vali Keel Vayu

9.Iyya Azhal Keel Vayu

10.Mukkutra Keel Vayu

AETIOLOGY:

According to *Yugi Vaithya Sinthamani,*

என்னவே வாதந்தா னெண்ப தாகும்
மிகுத்திலே மனிதகர்களுக் கெய்து மாறு
பின்னவெ பொந்தனையே சோரஞ் செய்து
பெரியோர்கள் பிராமணரைத் தூஷ் ணித்தும்
வன்னவேவச்சொத்திற் சோரஞ் செய்து
மாதாபித குருவ மறந்த பேர்க்கும்
கன்னவே வேத்தை 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 வரன்றன்னெளயெ மதியா மாந்தர்
அகதிபர தேசியர்கட் கன்ன மீயார்
கோனன குரமொழியை மறந்த பேர்கள்
கொலைகளவு பொய்காமங் குறித்த பேர்க்கு
ஊனான சடந்தன்னில் வாதம் வந்து
உற்பவிக்கும் வேதத்தி லுண்மை தானே.

யூகி வைத்திய சிந்தாமணி

According to the saint *Yugis* in his work, those who are squandering money, insulting the elders, blaspheming the Holy books, not respecting the divine gifts, abandoning or forgetting the parents having wickedness in their mind and those with

sleeping in the day time and awake up during night will get *Vaatham* disease, hot, taste, increased intake of water, excessive starvation, increased intake of bitter and astringent taste, increased sexual indulgence desire will produce *Vaatha* disease.

In the above literature saint *Yugimuni* said that the *Vaatha* diseases are precipitated in the months from *Aani* to *Karthigai* (June to December), hence the seasonal factors are involved and facilitate the *Vaatha* diseases.

FACTORS THAT INFLUENCE THE *VATHA* TYPE OF DISEASES:

கால இயல்பு– Environmental Factors:

Relation between occurrence of *Vaatha* Diseases and Seasonal variations:

"ஆடியாதியாய் ஐப்பசி ஈறா
அணிலமதற்ன் கோரரசியல் காலம்."

Vaatham elevates in the body from the month of *Aadi* to *Iyppasi* (July to September) i,e from the middle of *Muthuvenil kaalam*, *Kaar kaalam* to half of *Koothir kaalam.*

To summarise, *Vaatha* diseases occur due to certain diet capable of increasing *vatham*, certain habits and environmental changes which elevates *vatham.*

Diet:

தொழில்பெறு கைப்புக்கார்த்தல் துவர்த்தல் விஞ்சுகினுஞ்
சோரும் கழையதாம் வரகு மற்றைப்பைந்தினை யருந்தினாலும்
எழில் பெறப்பலுறங்கி இரவினிலுறங் காததாலும்
மழை நிகர் குழலினாலெ வாதங்கோ பிக்குங் காணே.

- பரராச சேகரம்

According to ***Pararasa sekaram*** , excess consumption of bitter taste, astringents and sour taste, inceased intake of old cooked rice, intake of grains, day time sleep and wake up at night time will get *Vaatham* diseases.

THE CLINICAL FEATUES OF AZHAL KEEL VAAYU IN *SABAABATHI KAIYEEDU* :

பித்தக்கீல் வாய்வு தன்னாற்
பிறக்குகீன் மூட்டு வீங்கிச்
சித்தர்செய் மருத்து வத்துஞ்
சீர்படாத் தன்மைத் தாகித்
தத்தறு காய்ச்சல் கண்டு
சாலவே தனைதான் தந்தே
மெத்தறு சிகிச்சை தன்னால்
மென்மேல் நீங்கு மப்பா.

சபாபதி கையேடு

It is characterised by pain, swelling and knee popping or cunching of the both knee joints.

DIAGNOSIS:

‘‘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.

Piniyarimuraigal (Method of Diagnosis) :

Piniyarimuraigal (Method of Diagnosis) is based upon the three main principles:

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

1. *Poriyalarithal* (Inspection):

"Poriyalarithal" means examining the *"Pori"* of the patient by the physician for proper diagnosis.

Pori-five sense organs.

They are as follows

- Nose
- Tongue
- Eye
- Skin
- Ear

2. *Pulanalarithal* (Palpation):

"Pulanalarithal" means examining the *"Pulan"* of the patient by the physician to diagnosis a disease.

Pulan- senses They are,

- Smell
- Taste
- Vision
- Sensation of touch
- Hearing

3. Vinaathal (Interrogation):

Vinaathal is gathering of information about the history of the disease, its clinical features etc., from the patient or his close relatives who are taking care of them. *Vinaathal* is helpful when the patient is not in a position to speak or when the patient is child.

Types of *Naadi* (Pulse) felt in *Azhal Keelvaayu:*

In Siddha system of Medicine *"Naadi* diagnosis (Pulse reading)" is the first and foremost diagnostic parameter.

In *Azhal Keel Vaayu* the following types of Naadi can be commonly seen.

They are,

Vaatha pitham

Vaatha kabam

Pitha vaatham

Kaba vaatham

DIFFERENTIAL DIAGNOSIS:

NOI KANIPPU VIVATHAM (DIFFERENTIAL DIAGNOSIS):

Azhal Keel Vayu is differentiated from the following diseases,

- ***VALI KEEL VAYU:***

  It is characterised by excruciating pain and swelling involving knee joints, hip joints, elbow joints, shoulder joints and associated with systemic disturbances like dryness of mouth, pyrexia, headache, palpitation, constipation and sweating. In advanced cases it may affect the heart .

- ***IYA KEEL VAYU:***

  It is characterised by severe pain in the joints associated with emaciation of the body, anorexia, insomnia, cough, hiccough, vomiting, anaemia and dropsy. The common sites are spinal cord, hip joints and knee joints.

- ***VALI IYA KEEL VAYU:***

  It is characterised by pain in the joints associated with effusions of joint fluid and swelling, restricted joint movements, pyrexia, fainting, insomnia, especially in knee joint asymmetrically, lymphadenopathy, generalized malaise, atrophy of the affected limb etc. The affected joint looks like "Fox‟s Head".

LINE OF TREATMENT

In Siddha system, the treatment is based upon the *Mukkutram* principle. Treatment is not only for perfect healing but also for the Prevention of disease progression and Rejuvenation of *Udalkattugal*.

While treating a disease, it is essential to know the etiology, the nature of the patient, severity of the illness, the seasons and the time of occurrence.

LINE OF TREATMENT IS AS FOLLOWS:

1.*Kaappu* (Prevention)

2.*Neekkam*(Treatment)

3.*Niraivu* (Restoration)

1.*KAAPPU* (PREVENTION):

"Prevention is better than cure" is a proverb. 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 in the underlying lines quoted from the text ***"Theraiyar Pinianuga Vithi"*** which emphasizes virtueness to be followed even in the daily life activities.i.e.,

பாலுண்போம் எண்ணெய்பெறின் வெந்நீர் குளிப்போம்
பகற்புணரோம் பகற்றுல்வோம் பாயோதரமு மூத்த
ஏலஞ்சேர் குழலியரோடி ளவெயிலும் விரும்போம்;
இரண்டடக்கோம்; ஒன்ரைவிடோம்; இடதுகையிற் படுப்போம்.

2.*NEEKAM* (TREATMENT INSIDDHA):

The aim of treatment is based on,

1. To bring the Three Thodams to normal equilibriumstate.
2. To treat the patient by Internal and externalmedicines.
3. To stabilize 7 Udalthadhukal and 3Uyirthadhukal.

To bring the three Thodams to normal equilibrium state first by giving purgation.

Diet Restrictions (*Pathiyam*):

During the course of treatment, the patients were advised to follow certain dietary regimen (Icha pathiyam) which is mentioned for *vaatha* diseases.

1. *Kadugu*
2. *Ell Nei*
3. *Kalyana Poosanikkai*
4. *Kadalai*
5. *Thengai*
6. *Mangai*
7. *Poondu*
8. *Pala*
9. *Kollu*
10. *Pugaiilai*
11. *Pagal*
12. *Agathi*
13. *Sourtaste*
14. *Astringenttaste*

3. *NIRAIVU* (RESTORATION):

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

MODERN ASPECTS ANATOMY OF JOINTS:

Joints can be classified as synovial, fibrous, or combination joints, based on the presence or absence of a synovial membrane and the amount of motion that occurs in the joint. Normal synovial joints allow a significant amount of motion along their extremely smooth articular surface.

The joints are composed of the following:

- Articular cartilage
- Subchondral bone
- Synovial membrane
- Synovial fluid
- Joint capsule.

The normal articular surface of synovial joints consists of articular cartilage (composed of chondrocytes) surrounded by an extracellular matrix that includes various macromolecules, most importantly proteoglycans and collagen. The cartilage protects the underlying subchondral bone by distributing large loads, maintaining low contact stresses and reducing friction at the joint. Synovial fluid is formed through a serum ultra filtration process by cells that form the synovial membrane (synoviocytes). Synovial cells also manufacture the major protein component of synovial fluid, hyaluronic acid (also known as hyaluronate). Synovial fluid supplies nutrients to the avascular articular cartilage; it also provides the viscosity needed to absorb shock from slow movements, as well as the elasticity required to absorb shock from rapid movements.

ANATOMY OF THE KNEE JOINT

Introduction:

The knee joint is the largest joint in the body, consisting of four bones and an extensive network of ligaments and muscles. Injuries to the knee joint are amongst the most common in sporting activities and understanding the anatomy of the joint is fundamental in understanding any subsequent pathology.

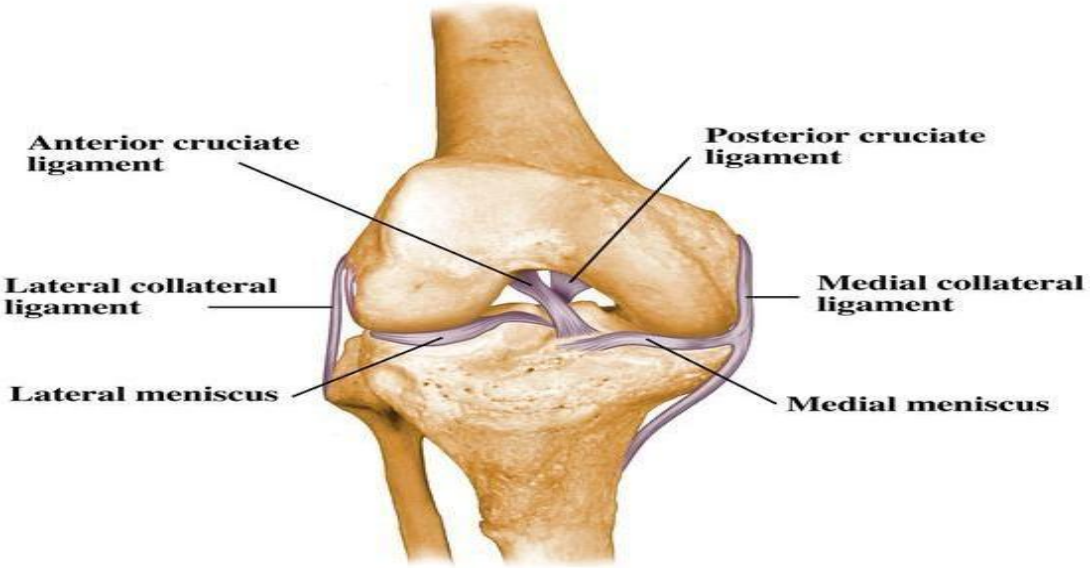
Bones of the knee joint:

The knee is made up of four main bones. The femur (thigh bone), the tibia (shinbone),fibula (outer shin bone) and patella (kneecap). The main movements of the knee jointoccur between the femur, patella and tibia. Each are covered in articular cartilage which is anextremely hard, smooth substance designed to decrease the frictional forces as movementsoccur between the bones. The patella lies in an indentation at the lower end of the femur known as the inter-condylar groove. At the outer surface of the tibia lies the fibula, a long thin bone that travels right down to the ankle joint.

The capsule:

The knee joint capsule is a thick ligamentous structure that surrounds the entire knee. Inside this capsule is a specialized membrane known as the synovial membrane which provides nourishment to all the surrounding structures. Other structures include the infrapatellar fat pad and bursa which function as cushions to exterior forces on the knee. The capsule itself is strengthened by the surrounding ligaments.

Ligaments of the knee joint:



The stability of the knee owes greatly to the presence of its ligaments. Each has a particular function in helping to maintain optimal knee stability in a variety of different positions.

Menisci (knee cartilage):

Each knee joints has two crescent shaped cartilage menisci. These lie on the medial and lateral edges of the upper surface of the tibia bone. They are essential components, acting as shock absorbers for the knee as well as allowing for correct weight distribution between the tibia and the femur.

LIGAMENTS AND MENISCI OF KNEE JOINTS

Two internal ligaments-the anterior and posterior cruciate ligament ligament also help to maintain the proper alignment of the knee. The anterior curciate ligament is the most anterior of these internal ligaments and extends obliquely from surface of the lateral condyle of the femur to the anterior intercondylar space of the tibia.

The ACL plays an important role in preventing hyperextension of the knee by limiting the anterior movement of the tibia. Directly behind the ACL is the posterior cruciate ligament PCL, which extends obliquely from the inner surface of the medial condyle of the femur to the posterior intercondylar space of the tibia. PCL prevents the posterior movements of the tibia relative to the femur.

Muscle groups surrounding the knee joint:

The two main muscle groups of the knee joint are the quadriceps and the hamstrings. Both play a vital role in moving and stabilizing the knee joint.

Quadriceps muscle:

The quadriceps muscle group is made up of four different individual muscles Which join together forming the quadriceps tendon. This thick tendon connects the muscle to the patella which in turn connects to the tibia via the patellar tendon. Contraction of the quadriceps, pull the patella upwards and leads to knee extension.

Hamstrings muscle:

The Hamstrings muscle function in flexing the knee joint as well as providing stability on either side of the joint line.

OSTEO ARTHRITIS (OA) :

INTRODUCTION:

OA is a degenerative joint disease involving the cartilage and many of its surrounding tissues. In addition to damage and loss of articular cartilage, there is remodeling of sub articular bone, osteophyte formation, ligamentous laxity, weakening of periarticular muscles and in some cases, synovial inflammation.

These changes may occur as a result of an imbalance in the equilibrium between the breakdown and repair of joint tissue. Primary symptoms of OA include joint pain, stiffness and limitation of movement. Disease progression is usually slow but can ultimately lead to joint failure with pain and disability. Osteoarthritis is abbreviated as OA or referred to as degenerative arthritis or degenerative joint disease (DJD).

EPIDEMIOLOGY:

International statistics:

The prevalence rises progressively with age and it has been estimated that 45% of all people develop knee OA and 25% hip OA at some point during life. Although some are asymptomatic, the lifetime risk of having a total hip or knee replacement for OA in someone aged 50 is about 11% for women and 8% for men in the UK. There are major ethnic difference in susceptibility : the prevalence of hip OA is lower in Africa,China , Japan and the Indian Subcontinent than in European countries , and that of knee OA is higher.

Pathophysiology:

OA is a complex disorder with both genetic and environmental components . Genetic factors are recognized as playing a key role in the pathogenesis of OA. Family –based studies have estimated that the heritability of OA ranges from about 43% at the knee to between 60% and 65% at the hip and hand, respectively, in most cases, the inheritance is polygenic and mediated by several genetic variants of small effect. OA can, however, be a component of multiple epiphyseal dysplasias, which are caused by mutations in the genes that encode components of cartilage matrix .Structural abnormalities, such as slipped femoral epiphysis and developmental dysplasia of the hip, are also associated with a high risk of OA, presumably due to abnormal load distribution across the joint. Similar mechanisms probably explain the increased risk of OA in patients with limb deformity secondary to Paget s disease of bone. Biomechanical factors play an important role in OA related to certain occupations, such as farmers, professional athletes .It has been speculated that the higher prevalence of knee OA in the Indian subcontinent and East Asia might be accounted for by squatting.There is also a high risk of OA in people who have had destabilizing injuries such as cruciate ligament rupture , and those who had meniscetomy.

For most individuals, however, participation in recreational sport does not appear to increase the risk significantly . There is a strong association between obesity and OA, particularly of the hip. This is thought to be due partly to biomechanical factors but it has also been speculated that cytokines released from adipose tissue may play a role. Oestrogen appears to play a role; lower rates of OA have been observed in women who

use hormone replacement therapy , and women who receive aromatase inhibitor therapy for breast cancer often experience a flare in symptoms of OA.

OA is a complex disease whose pathogenesis includes the contribution of biomechanical and metabolic factors which, altering the tissue homeostasis of articular cartilage and subchondral bone, determine the predominance of destructive over productive process. A key role in the pathophysiology of articular cartilage is played by cell/extra cellular matrix interactions, which are medited by cell surface intergrins.In a physiologic setting, intergrins modulate cell/ECM singnaling, essential for regulating growth and differentiation and maintaining cartilage homeostasis. During OA, abnormal intergrins expression alters cell/ECM signaling and modifies chondrocyte synthesis, with the following imbalance of destructive cytokines over regulatory factors.IL-1, TNF-alpha and other pro-catabolic cytokines activate the enzymatic degradation of cartilage matrix and are not counterbalanced by adequate synthesis of inhibitors. The main enzyme involved in ECM breakdown are metalloproteinases, which are sequentially activity by an partially inhibited by the tissue inhibitors of MMPs, whose synthesis is low compared with MMP productin in OA cartilage. Intriguing is the role of growth factors such as TGF-beta, IFG, BMP,NGF, and others ,which do not simply repair the tissue damage induced by catabolic factors, but play an important role in OA pathogenesis.

Symptoms of OA:

- Pain
- Swelling
- Stiffness in th knee joint
- Decrease in mobility of the knee.
- Creaking, crackly sound that is heard when the knee moves.

DEFORMITY:

Deformity can occur with osteoarthritis due to bone growths and cartilage loss. Bone growths in the end joints of the fingers are called Heberden‘s nodes. Bouchard‘s nodes are bone growths in the middle joints of the fingers. Degeneration of knee cartilage can result in the outward curvature of knee (bow- leggedness).

CLASSIFICATIONS:

It could be divided into 2 types :

1. Primary or idiopathic osteoarthritis
2. Secondary osteoarthritis

1.Primary or idiopathic osteoarthritis:

It is due to wear and tear changes occurring in old age in which the weight bearing joints like the hips and knees are more commonly affected. It is uncommon in non-weight bearing joints like the shoulder and elbow. Obesity is a predisposing factor.

2.Secondary osteoarthritis:

It is due to an abnormal wear and tear in a joint, caused by mechanical incongruity of the articular surfaces. This incongruity is due to the

- Mal-union of fractures involving the articular surfaces of tibia, femur orpatella
- Loose bodies in the joint
- Mal alignmentof the bones due to deformity like genu valgum or genu varum.

ETIOLOGY:

PRIMARY CAUSE OF OSTEOARTHRITIS:

The real cause is abnormal stress and strain on the joints associated with loss of mucopolysaccharide content of the matrix of the articular cartilage.

Though exact cause is not known, the following factors are suspected to play an important role in the causation of primary osteoarthritis

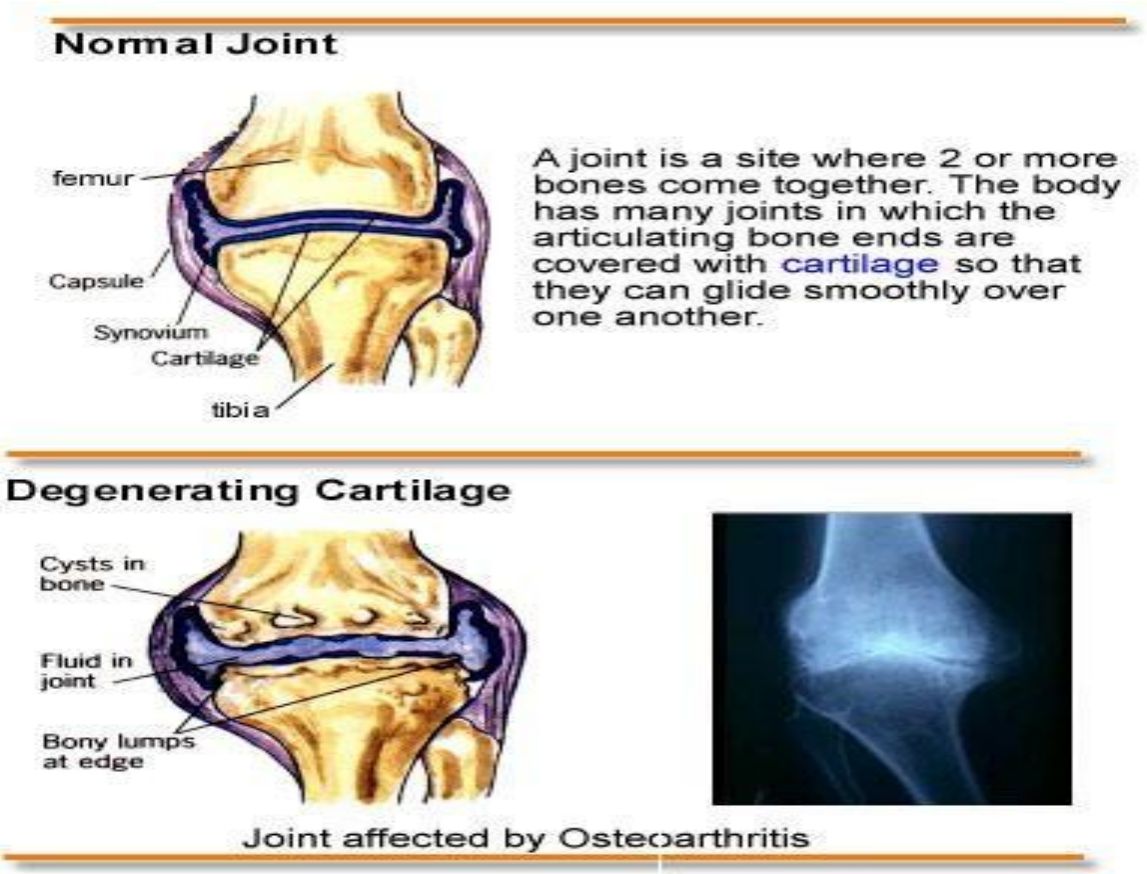
- Endocrine
- Post Traumatic
- Inflammatory joint disease
- Metabolic
- Congenital or developmental
- Genetic
- Neuropathic and others

SECONDARY CAUSES OF OSTEO ARTHRITIS:

The causes for secondary osteoarthritis of the knee are as follows:

- Obesity
- Rheumatoid arthritis, infection, trauma, TB, etc.
- Hyper parathyroidism.

DIFFERENCE BETWEEN NORMAL AND ARTHRITIC JOINT



RISK FACTORS :

Factors that increase your risk of osteoarthritis include:

- Older age:

  The risk of osteoarthritis increases with age.

- Bone deformities:

  Some people are born with malformed joints or defective cartilage, which can increase the risk of osteoarthritis.

- Joint injuries:

  Injuries, such as those that occur when playing sports or from an accident, may increase the risk of osteoarthritis.

- Obesity:

  Carrying more body weight puts added stress on your weight-bearing joints, such as your knees.

INVESTIGATIONS:

X-Ray :

a. Radiological features: The earliest change seen is the asymmetrical narrowing of the joint space and subchondral sclerosis in the medial compartment of the joint. Later, osteophytes are seen in the periphery of the articular surfaces of the femur, tibia and patella.

b. Arthroscopic Examination

It allows direct inspection and visualization of the damaged joint surface.

c. Synovial fluid Analysis

Shows non-inflammatory picture

d. Bone scan

e. CT

f. MRI

VARMAM:

Varmam is a science dealing with the impact to innumerable nerve junctions of the human body. The changes occurring in the body on being hit at some specific points directly or indirectly with a particular force is known as *Varmam.*

In human body from the head to toe there are numerous *varmam*.

Varmam is considered as one of the unique branch in Siddha system of medicine. Since ancient days it has been developed and used as martial of defensive art and also used in medical healing practice. According to Siddha literature, *Varmam* therapy is considered as "Vital points therapy" by which the diseases are healed by manipulating some pressure points either by touch or massage.

This *Varmam* points may be the nerve junctions, muscular junction or the points that the *Pranan* lived.

Varmam is the vital life energy points located in human body and was identified as 108 points by the *Siddhars*. When these points are hit with a particular force directly or indirectly, pathological changes occur in the body. The intensity of the changes depends on the force of hitting that particular point, the duration exposed to the force and physical strength of the affected person.

The effects observed when *Varmam* point is affected are pain, swelling, bleeding (at the hit site or near the corresponding natural orifice, spasm of the limbs, loss of function of the vital organs, vomiting, protrusion or in-drawing of the tongue, in-drawing or herniation of testicles, protrusion of eyeball, breathlessness, fainting and even death may result.

The term *Varmam* also indicates the therapeutic manipulation of specific points in which the pranic energy is found concentrated. Manipulation over these points with a particular force for the specific time will release the pranic energy from these points and brings relief to the affected individual by regulating the flow of pranic energy which is obstructed due to assault on specific points (*Varmam* points) or due to other cause.

In our lifestyle *Varmam* is the major cause for muscular strain, sprain, joint pain and low back pain. It is present in our inner aspect of our body. So it is otherwise called a *MARMAM*. On the other hand the name *Marmam* mean that the point should be keep as secret.

Varmam energy circulation *(Sara ottam)*:

"Utaluyir nadithannil unthidum vaasiyathaam
Oonudal maruviye oodadum nilaiye varmam"

According to *Varmam Sara Nool*, Human body consist of a vital energy circulation that passes continuously and transmits energy to the whole body. This ciuculation is called as ―*Varma* energy circulation (*Sara Ootam*) and the energy that passes through is called as *"Saram* or *Vaasi"*

Thasanadis are the vital energy channels by which the energy circulation takes place. The energy that passes will retained, stored and transmitted in certain areas or points of human body and that points are called as *Varmam* points or Vital points. In our Siddha literature *Varmam* is basically divided into two parts They are

1. Medicinal aspect
2. Defence & offence aspect

SYNONYMS AND OTHER NAMES OFVARMAM:

Kalam, Adakkam, Marmam, Sutcham, Vanmam, Emam, Idu , Karuvi, Kalai, Seevan Swasam, Puravi, etc..

Varmam–Art as well as science:

Varmam is an art as well as a science. As an art it can be employed to attack a person to make a permanent or temporary disability to a person (which is normally not done) .It is also a science, it helps treat persons from the impact arising from traumatic injuries.

CLASSIFICATION OF *VARMAM*:

There are 2 major classification present in *Varmam*

They are classified as below

1. *Padu varmam*

2. *Thodu varmam*

VARMAM POINTS TO BE MANIPULATED IN AZHAL KEEL VAYUPATIENTS:

- *Kaal Moottu Varmam*
- *Komberi Varmam*
- *Viruthi*
- *Ullangal vellai*

KAAL MOOTTU VARMAM:

Synonyms:

- மூட்டு வர்மம் (வர்ம சூத்திரம்-101)
  (கண்ணாடி-500)
- கால் மூட்டு வர்மம் (வர்ம விரலளவு நூல்)

Location:

"தானதிலே முட்டிசைவில் **மூட்டு வர்மம்**" (வர்ம கண்ணாடி-500)

Located in the popliteal fossa

KOMBERI VARMAM :

Synonyms:

- தும்பிக்கால வர்மம் (வர்ம நூலளவு நூல்)
- கொம்பேறி வர்மம் (வர்ம சூத்திரம் 101)

Location:

"ஏகும் முடவு இறைரண்டில் **தும்பிக்காலம்**" (அடிவர்ம சூட்சம்-500)

Located at the centre of the medial aspect of the leg.

VIRUTHI VARMAM:

Synonyms:

விற்தி வர்மம் (வர்ம கண்ணாடி-500)

விர்த்தி வர்மம் (அடிவர்ம சூட்சம்-500)

Location:

"போமென்ற பெருவிரல் மொழி மேல் **விர்த்த காலம்**" (அடிவர்ம சூட்சம் 500)

Located in the space in between the great toe and second toe on the dorsum of the foot.

ULLANGAL VELLAIVARMAM:

Synonyms:

வெள்ளை வர்மம் (வர்ம ஒடிவுமுறிவு சசூத்திரம் -1200)

அடங்கல் வர்மம் (வர்ம சூத்திரம் 101)

உள்ளங்கால் வர்மம் (வர்ம விரலவு நூல்)

Location:

"அகமான உள்ளம் கால் **வெள்ளை வர்மம்**" (அடிவர்ம சூட்சம் 500)

Located on the depression in between the eminences of great toe and second toe in the plantar aspect of the foot

DRUG REVIEW

PROPERTIES OF TRAIL DRUG

INTERNAL MEDICINE *: KANDATHRI CHOORANAM*

INJI

Botanical name	:	*Zingiber officinale*
Family	:	Zingiberaceae
Parts used	:	Rhizome

Organoleptic characters

Taste	:	*Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions:

- Carminative
- Stomachic
- Digestive.

Chemical constituents:

- Gingerol
- Paradols
- Shogaol,
- Glycosides,
- Terpenoids,
- saponins.

General characters :

"இஞ்சிக் கிழங்குக் கிருமல் ஓக்காளம்
வஞ்சிக்குஞ் சன்னிசுரம் வன்பேதி -விஞ்சுகின்ற
சூலையறும் வாதம்போந் தூண்டாத தீபனமாம்
வேலையுறுங் கண்ணோய்".

(அகத்தியர் குணவாகடம்)

SEERAGAM

Botanical name	:	*Cuminum cyminum*
Family	:	Apiaceae
Parts used	:	Seed

Organoleptic characters

Taste	:	*Kaarppu, Inippu*
Potency	:	*Thatppam*
Division	:	*Inippu*

Actions:

- Carminative
- Stomachic
- Astringent.

Chemical constituents:

- Terpinene
- Limonene
- Safranal,
- β-pinene
- Vitamins B and E
- Cymene.

General characters :

"போசன குடாரியைப் புசிக்கில்நோ யெலாமறுங்
காசமி ராதக் காரத்தி லுண்டிட".

(தேரன் - வெண்பா)

MILAGU

Botanical name	:	*Piper nigrum*
Family	:	Piperaceae
Parts used	:	Seed

Organoleptic characters

Taste	:	*Kaippu, Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions:

- Carminative
- Antivatha
- Antidote

Chemical constituents:

- Piperine
- Phellandrene
- Linalool
- Limonen
- Pinen

General characters :

"கோணுகின்ற பக்கவலி குய்யவுரோ கம்வாத
சோணிதங்க முத்திற்குள் தோன்றுநோய்-காணரிய
காதுநோய் மாதர்குன்மங் காமாலை மந்தமென்றீர்
ஏதுநோய் காயிருக்கில் ஈங்கு". **(அகத்தியர் குணவாகடம்)**

THALISAPATHIRI

Botanical name	:	*Abies spectabilis*
Family	:	Pinaceae
Parts used	:	Dried leaves

Organoleptic characters

Taste	:	*Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions:

- Carminative
- Stomachic
- Epectorant

Chemical constituents:

- A-pinene
- β-phellandrene
- Tannins
- Alkaloids
- Steroids
- Glycosides

General characters :

‘‘நாசி களப்பிணிகள் நாட்பட்ட்-காசஞ்சு
வாசம் அருசி வனமங்கால்-வீசிவரு
மேகமந்தம் அத்திசுரம் விட்டேகுந் தாளிசத்தால்
ஆகுஞ் சுகப்பிரச வம்”. **(அகத்தியர் குணவாகடம்)**

THIPPILIMOOLAM

Botanical name	:	*Piper longum*
Family	:	Piperaceae
Parts used	:	Root

Organoleptic characters

Taste	:	*Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions :

- Stomachic.

Chemical constituents:

- Saponins
- Ketones
- Aldehydes
- Phytols
- Piperine
- Sabinene
- Chavicin,
- Limonene,
- β-caryophyllene
- Piperyline
- Phellandrene

General characters :

“தாகபித்தஞ் சோகந் தணியாச் சுரமிருமல்
மேகங் குரற்கம்மல் மெய்க்கடுப்பும்-ஏகுங்காண்
திப்பிலிமூ லங்கண்டத் திப்பிலிய தாம்நறுக்குத்
திப்பிலியென் றேயொருக்கற் செப்பு”. **(அகத்தியர் குணவாகடம்)**

KIRAMBU

Botanical name	:	*Syzygium aromaticum*
Family	:	Myrtaceae
Parts used	:	Dried bad

Organoleptic characters

Taste	:	*Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions:

- Carminative
- Antispasmodic
- Stomachic

Chemical constituents:

- Carcacrol
- Thymol
- Eugenol

General characters :

“பித்த மயக்கம் பேதியொடு வாந்தியும்போம்
சுத்தவிரத் தக்கடுப்புந் தோன்றுமோ-மெத்த
இலவங்கங் கொண்டவருக் கேற் சுகமாகும்
மலமங்கே கட்டுமென வாழ்த்து”. **(அகத்தியர் குணவாகடம்)**

KOTTAM

Botanical name	:	*Costus speciosus*
Family	:	Costaceae
Parts used	:	Root

Organoleptic characters

Taste	:	*Kaippu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions :

- Stomachic
- Tonic
- Expectorant

Chemical constituents:

- Tigogenin
- Diosgenin
- Tetracosanoic acid
- Succinicacid
- β-sitosterol

General characters :

“நாட்டிலுறு வெட்டை நடுக்கம் எனுநோய்கள்
கோட்டமெனச் சொன்னால் குலையுங்காண்-கூட்டிற்
சுரதோடந் தொண்டைநோய் தோலாத பித்தம்
பரதேசம் போமே பறந்து”. **(அகத்தியர் குணவாகடம்)**

VAIVILANGAM

Botanical name	:	*Embelia ribes*
Family	:	Primulaceae
Parts used	:	Seed

Organoleptic characters

Taste	:	*Kaippu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions :

- Carminative
- Stomachic
- Anthelmintic .

Chemical constituents:

- Embelin
- Christembine
- Quercitol
- Sitosterol
- Tannin
- Cinnamic acid
- Chrorogenic acid

General characters :

“பாண்டுகுட்டம் குன்மம் பருந்தூல நோய்வாதந்
தீண்டு திரிவிடஞ் சிரந்துண்டம்-பூண்டமடி
நோய்விளங்கக் காட்டாத நுண்கிருமி யாசனப்புண்
வாய் விளங்கக்காட்ட விருமார்”. **(அகத்தியர் குணவாகடம்)**

SARKARAI

Botanical name : *Borassus flabellifer*

Family : Arecaceae

Parts used : Fruit

Organoleptic characters

Taste : *Inippu,Thuvarppu*

Potency : *Thatppam*

Division : *Inippu*

Actions :

- Nutrient
- Diuretic
- Astringent

Chemical constituents:

- Albuminoids
- Fats
- Steroids

General characters :

“.....தங்குபனை வெல்லத்தால் வாதபித்தம் வீறுகபஞ் சன்னிநோய் வல்லருசி குன்மறு மால்”.

EXTERNAL MEDICINE : ERANDAI THYLAM
AMANAKKU ENNAI

Botanical name	:	*Ricinus communis*
Family	:	Euphorbiaceae
Parts used	:	Seed

Organoleptic characters

Taste	:	*Kaippu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions:

- Anti-vatha
- Laxative

General characters :

“வாதத் தொடக்கை வரவொட்டா மற்படிக்குக்
காதத்துக் காப்பாற் கடியுமே-சூதத்தைப்
பேரண்டப் பந்திக்கும் பேதிக்கு நோய்க்காட்டை
யேர்ண்ட மென்பதினியே”. **(அகத்தியர் குணவாகடம்)**

MILAGU

Botanical name	:	*Piper nigrum*
Family	:	Piperaceae
Parts used	:	Seed

Organoleptic characters

Taste	:	*Kaippu, Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions :

- Carminative
- Anti-vatha
- Antidote

General characters :

“கோணுகின்ற பக்கவலி குய்யவுரோ கம்வாத
சோணிதங்க முத்திற்குள் தோன்றுநோய்-காணரிய
காதுநோய் மாதர்குன்மங் காமாலை மந்தமென்றீர்
ஏதுநோய் காயிருக்கில் ஈங்கு”. **(அகத்தியர் குணவாகடம்)**

VELLAI POONDU

Botanical name	:	*Allium sativum*
Family	:	Amaryllidaceae
Parts used	:	Rhizome

Organoleptic characters

Taste	:	*Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions:

- Carminative
- Stomachic
- Expectorant
- Diuretic

General characters :

“சன்னியொடு வாதந் தலைநோவு தாள்வலி
மன்னிவரு நீர்க்கோவை வன்சீதம்-அன்னமே
உள்ளிள்ளி கண்பாய் உளைமூல ரோகமும் போம்
வெள்ளுள்ளி தன்னால் வெருண்டு”. **(அகத்தியர் குணவாகடம்)**

MANJAL

Botanical name	:	*Curcuma longa*
Family	:	Zingiberaceae
Parts used	:	Rhizome

Organoleptic characters

Taste	:	*Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions :

- Carminative
- Hepatic tonic
- Stimulant

General characters :

“பொன்னிறமாம் மேனி புலனாற்ற மும்போகும்
மன்னு புருட வசியமாம்-பின்னியெழும்
வாந்திபித்த தோடமையம் வாதம்போந் தீபனமாங்
கூர்ந்தமஞ்ச ளின்கிழங்குக்கு”. **(அகத்தியர் குணவாகடம்)**

KADUGU

Botanical name	:	*Brassico juncea*
Family	:	Brassicaceae
Parts used	:	Seed

Organoleptic characters

Taste	:	*Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions :

- Emetic
- Stimulant
- Digestive
- Diuret

General characters :

“மந்தம்மயக் கம்வாதம் வாய்நீர்ச் சுழற்றலறு
முந்து சுகப்பிரச வங்களுண்டா-மிந்துநுதன்
மானே கிராணிகுன்ம மாறுமுத் தொடமும்போம்
தானே கடுகிற்குத் தான்”. **(அகத்தியர் குணவாகடம்)**

KUPPAIMENI

Botanical name	:	*Acalypha indica*
Family	:	Euphorbiaceae
Parts used	:	Leaves

Organoleptic characters

Taste	:	*Kaippu, Kaarppu*
Potency	:	*Veppam*
Division	:	*Kaarppu*

Actions :

- Emetic
- Expectorant
- Anodyne
- Diuretic
- Anthelmintic

General characters :

“தந்தமூ லப்பிணிதீத் தந்திடீபுண் சர்வவிடம்
உந்துகுன்மம் வாதம் உதிரமூ-லந்தினவு
சூலஞ்சு வாசம் தொடர்பீ சங்கபம்போம்
ஞாலங்கொள் மேனியத னால்” (தேரன்-குணவாகடம்)

INGREDIENTS OF INTERNAL MEDICINE:

KANDATHRI CHOORANAM

INGI

SEERAGAM

MILAGU

THALISAPATHIRI

THIPPILI MOOLAM

KIRAMBU

KOTTAM

VAI VILANGAM

SARKKARAI

INGREDIENTS EXTERNAL MEDICINE:

ERANDAI THYLAM

AAMANAKKU ENNAI

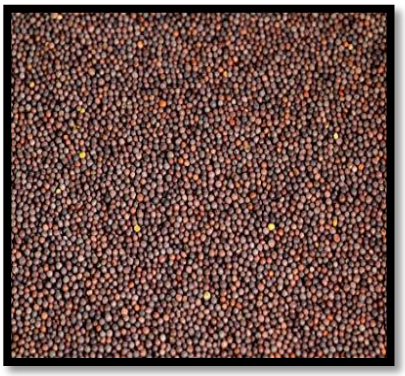
MILAGU

POONDU

e

MANJAL

KADUGU



KUPPAIMENI

MATERIALS AND METHODS

To evaluate the therapeutic efficacy of Siddha herbal formulation of *"**Kandathiri chooranam**"*(Internal) and **"*Erandai Thailam*"(**External) for **"*Azhal Keel Vayu*"** (Osteo Arthritis of Knee joint).

STUDY DESIGN:

An open clinical trial

STUDY PLACE:

Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47

DISEASE CONDITION:

- Pain
- Swelling
- Stiffness
- Crepitation
- Tenderness
- Warmth
- Restricted movements.

STUDY PERIOD: 18 months

SAMPLE SIZE: 40 patients

(20 patients will be treated with trail medicine; 20 patients will be treated with trail medicine along with Varmam therapy.**)**

DRUG FORMULATION:

INTERNAL MEDICINE:

Drug	:	***KANDATHIRI CHOORANAM***
Reference book	:	*Agasthiyar Vaithiya Rathina Churukkam*
Page No	:	46 & 47
Dosage	:	1250 -1500 mg (Verukadi)
Adjuvant	:	Cold water
Duration	:	48days (1 Mandalam)
Edition	:	2nd Print, Feb-1998.
Author	:	S.T.Ramachandran
Publication	:	Thamarai Noolagam

EXTERNAL MEDICINE:

Drug	:	***ERANDAI THAILAM***
Dosage	:	Q.S (for external application)
Reference	:	*Saravendhira Vaithiya Muraigal*
Page no	:	12
Edition	:	4th Print, Nov-1998.
Author	:	K.Vasudheva Sasthiri
Publication	:	Saraswathi Noolagam

VARMAM POINTS TO BE APPLIED TO THE PATIENT:

- *Kaal Mootu Varmam (Varma Viralalavu Nool)*
- *Komberi (Varma soothiram 101)*
- *Viruthi (Varmalaada soothiram 300)*
- *Ullangal Vellai (Adivarma sootcham 500)*

INCLUSION CRITERIA:

- Age : 30-65 Yrs
- Sex : Both male and female

- Patients having symptoms of arthritis of both knee joints, Pain, swelling, stiffness, crepitation, restricted movements of knee joint.
- Patients who are willing to undergo radiological investigation, Laboratory investigations.
- Patients willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48days but can opt out of the trial of his/her own conscious discretion.

EXCLUSION CRITERIA:

- Cardiac diseases
- Rheumatoid arthritis
- Pregnancy and lactation
- Patient with any other serious systemic illness
- Chronic kidney disease
- Tuberculosis of knee
- Septic arthritis
- Gonococcal arthritis
- H/o Diabetes mellitus

WITHDRAWAL CRITERIA:

- Intolerance to the drug and development of adverse reactions during drug trial.
- Poor patient compliance and defaulters.
- Patient turning unwilling to continue in the course of clinical trial.
- Occurrence of any serious illness

TESTS AND ASSESSMENTS:

A. Clinical assessment
B. Laboratory investigations
C. Radiological investigations
D. Siddha system assessment.

B. Routine investigation

Blood:

- Hb
- Total WBC Count
- DC- Polymorphs
    1. Lymphocytes
    2. Eosinophil
    3. Monocytes
    4. Basophils
- Total RBC count
- ESR

  ½ Hr: 1 Hr:
- Blood sugar

  Fasting: PP:

Urine:

- Albumin
- Sugar
- Deposits

Renal function tests:

- Urea
- Creatinine

Liver function tests:

- Serum total bilirubin
- Direct bilirubin
- Indirect bilirubin
- Serum Alkaline phosphatases
- SGOT
- SGPT

SPECIFIC INVESTIGATIONS:

- CRP
- ASO TITRE
- RA FACTOR

C. RADIOLOGICAL INVESTIGATIONS

X- Ray Knee joints (AP and Lat view)

D. SIDDHA PARAMETERS:

Envagai thervugal:

Naadi

Sparisam

Naa

Niram

Mozhi

Vizhi

Malam

Moothiram

- NeerkKuri
- Neikkuri.

STANDARD OPERATIVE PROCEDURE

Source of Trial Medicine:

The required raw drugs for the preparation of *"Kandathiri Chooranam"* (internal) and *"Erandai Thailam"* (external)will be purchased from a well reputed country shop and the raw drugs will be authenticated by the competent authority (medicinal botany and gunapadam department). After that the raw drugs will be purified separately and the medicine will be prepared in Gunapadam laboratory of National institute of Siddha.

Purification of raw drugs:

Inji (*Zingiber officinale*)

To be outer layer removed.

Seeragm (*Cuminum cyminum*)

To be dried under sunlight without any dust particle

Milagu (*Piper nigrum*):

To be dired under sunlight without any dust particle.

Thalisapathiri (*Abie sspectabilis*)

To be dired under sunlight without any dust particle.

Thippili moolam (*Piper longum*)

To be dry under sunlight without any dust particle.

Kirambu (*Syzygium aromaticum*)

To be dried under sunlight without any dust particle.

Kottam (*Costus speciosus*)

To be dried under sunlight without any dust particle.

Vai vilangam (*Embelia ribes*)

To be dried under sunlight without any dust particle.

Sarkkarai *(Borassus flabellifer)*

To be clean the dust particles

Reference:

Sikitcha Rathina Deepam ,Saraku Suthi Muraigal.

Method of Preparation:

Take ginger(10 palam) with outer skin removed and then cut in to small pieces. Then soak that ginger piece in lemon juice for one day. Then dry that soaked over sun on next day.

Then take 1 palam of cumin and soak that in lemon juice for one day. Then dry that soaked cumin over sunlight on next day. Purify and powder the below raw drugs and then add same amount of sugar .

Inji
Seeragam
Milagu
Thalisapathiri
Thippilimoolam
Kirambu
Kottam
Vaivilangam

B.External Medicine:

Ingredients:

- Amanakku Yennai *(Ricinus communis)* - ½ palam (17.5 gm)
- Milagu *(Piper nigrum*) - ½ palam (17.5 gm)
- Manjal *(Curcuma longa*) - ½ palam (17.5 gm)
- Kadugu (*Brassiajuncea*) - ½ palam (17.5 gm)
- Vellai poondu (*Allium sativum)* - ½ palam (17.5 gm)
- Kuppaimeni charu (*Acalyphaindica*) - ½ padi (670 ml)

Purification of drugs:

Amanakku yennai (*Ricinus communis*)

To be take amanakku yennai in a vessel and place that vessel in sand with exposure to sun.

Milagu (*Piper nigrum*):

To soak pepper in butter milk for 1 hr 15 mins and then rost it.

Vellai Poondu (*Allium sativum*)

To be remove the outer layer.

Kadugu (*Brassia juncea*)

To be take the mustard in a vessel and place that vessel in sunlight for two days.

Manjal *(Curcuma langa)*

To be remove the out layer and then cut into small pieces. To be dried under sunlight.

Kuppaimenicharu (*Acalypha indica)*

To be washed with water and dry it.

Reference:

Sikitcha Rathina Deepam.

Method of preparation:

All the above ingredients except kuppaimeni are taken in equal proportion (1/2 palam) and powdered well and mixed.Take one vessel, Then add ½ padi of kuppaimeni saru and place that in sunlight and add other powdered drugs.then add aamanakku ennai then heat for sometime in the evening.Then it should be stored in dry container.

Drug storage:

The trial drug *"Kandathiri Chooranam"* is stored in clean and dry container and *"Erandai Thylam"*is stored in clean and dry narrow mouthed bottles.

Dispensing:

The Chooranam is given in packets and oil is given in bottles.

OUTCOME:

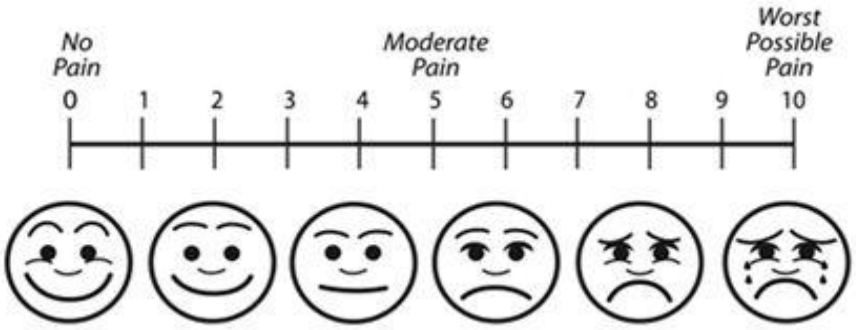
A. Outcome of the study will be assessed by the following:

1. Universal Pain assessment scale
2. Questionnaire of Osteoarthritis :

1.UNIVERSAL PAIN ASSESMENT SCALE:

Pain Intensity Scale: 0 to 10

(from Simkin, P. (2010), Pain Medications for Labor & Birth (PowerPoint). Waco, Childbirth Graphics



Grade 0 : No Pain

Grade 1 -3 : Mild pain

Grade 4-6 : Moderate pain

Grade 7-10 : Severe pain

OUTCOME:

0 : Good improvement

1-3 : Moderate improvement

4-6 : Mild improvement

7-10 : No improvement

B. Questionnaire of Osteoarthritis :

Name
Age

Which knee is bothering you?

Right Left Both
Did your knee pain start with a specific injury?

Yes No
If yes: Date of injury:
Mechanism of injury :

Did you feel a pop or snap with the injury?

Yes No
Is the injury work related?

Yes No
Did your pain start with a particular sport or activity?

Yes No
If yes, what started the pain?

If there was no injury, when did the pain start?

What part of your knee hurts? Front Inside Outside Back
What are your primary sports and/or activities?

How would you describe your pain? (constant, intermittent, mild, severe, etc.)

Do any of the following increase your pain?

Prolonged walking: Yes Minimally No

Prolonged standing: Yes Minimally No

Going up or down stairs: Yes Minimally No

Prolonged sitting: Yes Minimally No
Getting up from a sitting position: Yes Minimally No

Kneeling or squatting: Yes Minimally No

Pivoting or twisting motions: Yes Minimally No

Running: Yes Minimally No

Sports: Yes Minimally No

Is there anything else that increases your pain?

Do any of the following decrease your pain?

Rest: Yes Minimally No

Ice: Yes Minimally No

Heat: Yes Minimally No

Do you have any of the following symptoms?
Weakness in your leg: Yes Minimally No

Giving way or buckling of your knee: Yes Minimally No

Locking of your knee (unable to fully straighten): Yes Minimally No

Clicking or catching in your knee: Yes Minimally No

Grinding sensation in your knee: Yes Minimally No

Swelling of your knee: Yes Minimally No

Stiffness: Yes Minimally No

Pain at night: Yes Minimally No

Numbness or tingling in your leg: Yes Minimally No

Are there any other symptoms that we need to know about regarding your knee?
Have you had any prior surgery to your knee(s)? Yes No

If yes, what type of surgery did you have and when did you have the surgery?

Have you had any prior treatment for your knee pain such as:

Cortisone injections: Yes No

Synvisc, Euflexxa or "Gel" injections: Yes No

Physical therapy: Yes No

Do you use any ambulatory aids (cane, crutches, walker) Yes No

Have you had any x-rays taken of your knee(s): Yes No

If yes: Date of x-rays:

X-ray facility

Have you had an MRI of your knee(s): Yes No

If yes: Date of MRI:
Is there anything else we need to know about your knee pain?

11. STUDY ENROLLMENT:

Patients reporting at the OPD with the clinical symptoms of *Azhal Keel Vayu* will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled would be informed (Form VI) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and informed consent would be obtained in writing from them in the consent form (Form VI).

All these patients will be given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctors phone number etc. will be given, so as to report easily should any complications arises.

Complete clinical history, complaints and duration, examination findings and laboratory investigations -- would be recorded in the prescribed Proforma. Patients will be advised to take the trial drug and to follow the appropriate dietary advice.

CONDUCT OF THE STUDY:

Purgation will be given with coarse of Meganaatha Kuligai-2 with Hot water at early morning in empty stomach will be given for balancing the deranged *mukkutram* a day before the treatment.

The trial drug *Kandathiri Chooranam* (Internal) and *Erandai Thailam* (External) are given continuously for 48 days. OPD patients are requested to visit the hospital once in seven days. In each and every visit clinical assessment is done and prognosis is noted in the Prescribed Proformas. For In patients clinical assessment is done daily. 20 patients will be given Varmam treatment along with trial medicines. Laboratory investigations and Radiological investigation are done on the before and the last day of the trial. Defaulters of will not be allowed to continue and be withdrawn from the study.

ETHICAL ISSUES:

1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of laboratory equipments will be used.
2. No other external or internal medicines will be used, other than the trial drug for osteoarthritis. There will be no infringement on the rights of the patient.
3. The data collected from the patient will be kept confidential.
4. After getting the consent of the patient only (through consent form in their own vernacular language) they will be enrolled in the study.
5. Treatment would be provided free of cost.
6. In any adverse reaction observed during the trial the patients will be given alternative treatment at National Institute of Siddha for further management.

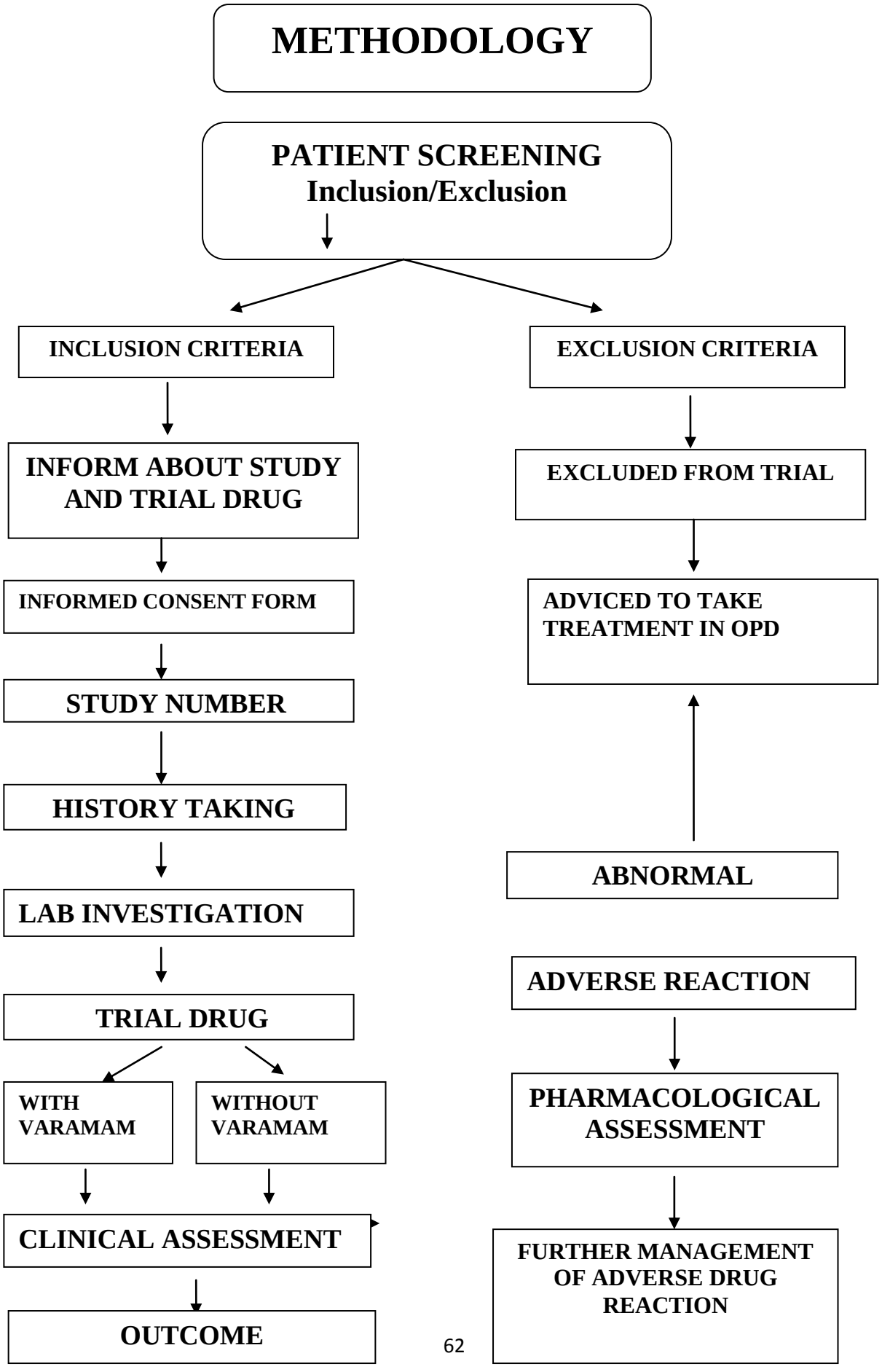
DATA COLLECTION FORMS:

Required information will be collected from each patient by using the following forms:

FORMS:

- Form I — Screening and selection Proforma
- Form II — History taking & Clinical assessment Proforma
- Form III — Laboratory investigation Proforma
- Form IV — Drug compliance form
- Form V — Patient information sheet
- Form VI — Consent form
- Form VII — Withdrawal form
- Form VIII — Dietary Advice form

METHODOLOGY



DATA ANALYSIS:

After enrolling the patient for the study, a separate file for each patient will be opened and all forms will be kept in the file. Study No. and Patient No. will be written on the top of file for easy identification. Whenever the patient visits OPD during the study period, the respective patient's file will be taken and necessary entries will be made at the assessment form or other suitable form. The screening forms will be filed separately. The data recordings will be monitored for completion and adverse event by HOD and pharmacovigilance committee. All forms will be further scrutinized in presence of Investigators by Sr. Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased report.

PHARMACOVIGILANCE:

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National Institute of Siddha and the same will be informed to the Pharmaco-vigilance committee of NIS.

References:

1.Text Book Of Orthopedics (John ebnezer pg.no:674)

2.www.ncbt.nlm.nih.gov

3.Varma PulligalinIrupidam (Kanan Rajaram)

4.Athma Ratchamirtham (Kandhasami Muthaliyar)

5.SikitchaRathinaDeepam (Kannusami Muthaliyar)

6.SiddhaMaruthuvamPothu (KuppusamiMuthaliyar)

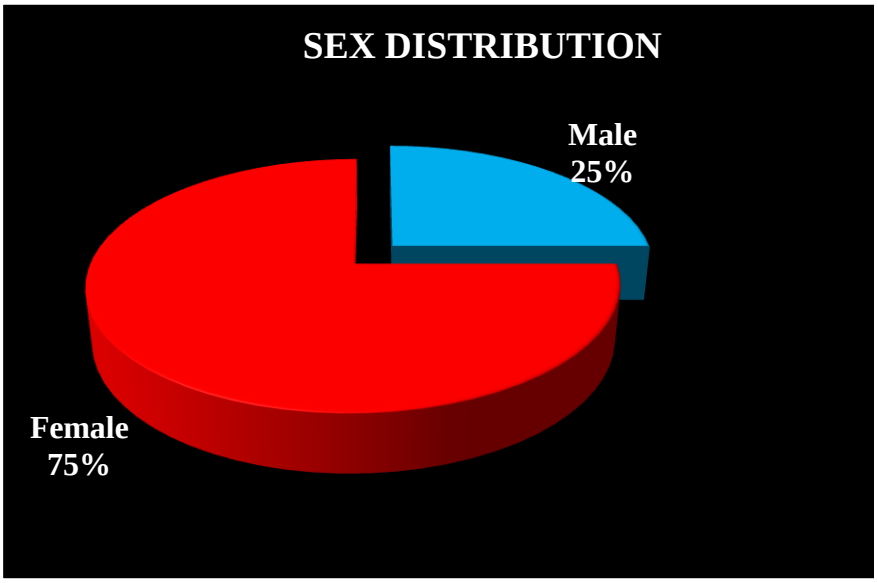
OBSERVATION AND RESULTS

Results of the study were observed with respect to the following criteria

1. Sex Distribution
2. Age Distribution
3. Socio Economic Status
4. Occupational Distribution
5. Duration of Illness
6. Diet
7. Thinai
8. Paruva Kalam
9. Gunam
10. Yaakai Ilakanam
11. Distribution of Vaatham
12. Distribution of Pitham
13. Distribution of Iyyam
14. Clinical Features
15. Envagai Thervu
16. Neikuri
17. Udal Thaathukkal
18. Kanmenthiriyam
19. Outcome Measures
20. Pain Assessment
21. Pain Assessment Scale
22. Result

1.SEX DISTRIBUTION:

Sl. No	Sex	No of Cases	Percentage
1	Males	10	25%
2	Females	30	75%

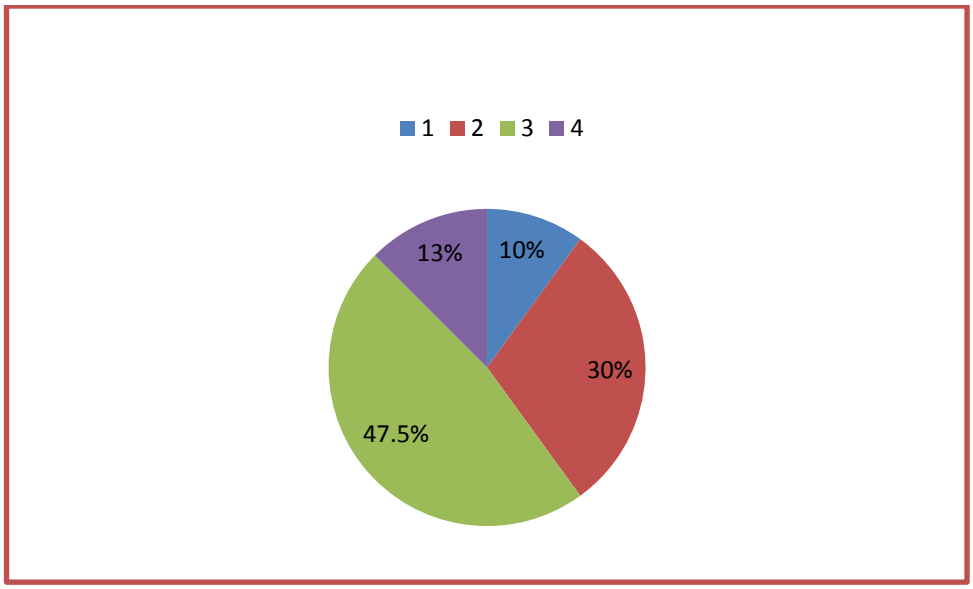


OBSERVATION:

Among 40 patients selected, the disease was found to be in high in females 75% and low in males 25%

2. AGE DISTRIBUTION:

Sl. No	Age	No of Cases	Percentage
1	30-40 years	4	10
2	41-50 years	12	30
3	51-60 years	19	47.5%
4	61-65 years	5	12.5%

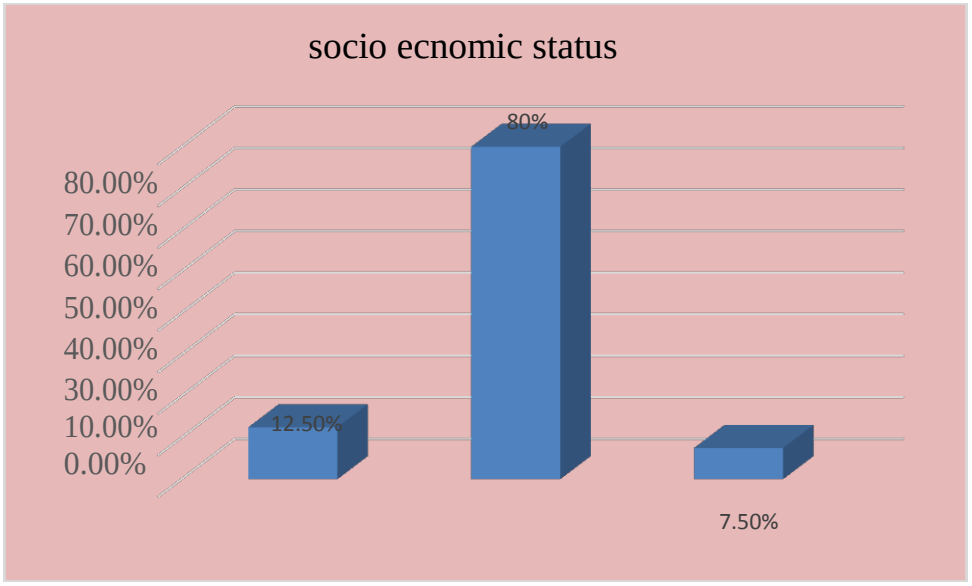


OBSERVATION:

10% of patients came under the age group between 30-40 years, 30% of patients fell under the age group between 41-50 years, 47.5% % of patients were between 51-60 years and 12.5% of patients were between 61-65years.

3.SOCIO ECONOMIC STATUS :

Sl. No	Socio economic status	No of Cases	Percentage
1	Low income	5	12.5%
2	Moderate income	32	80%
3	High income	3	7.5%

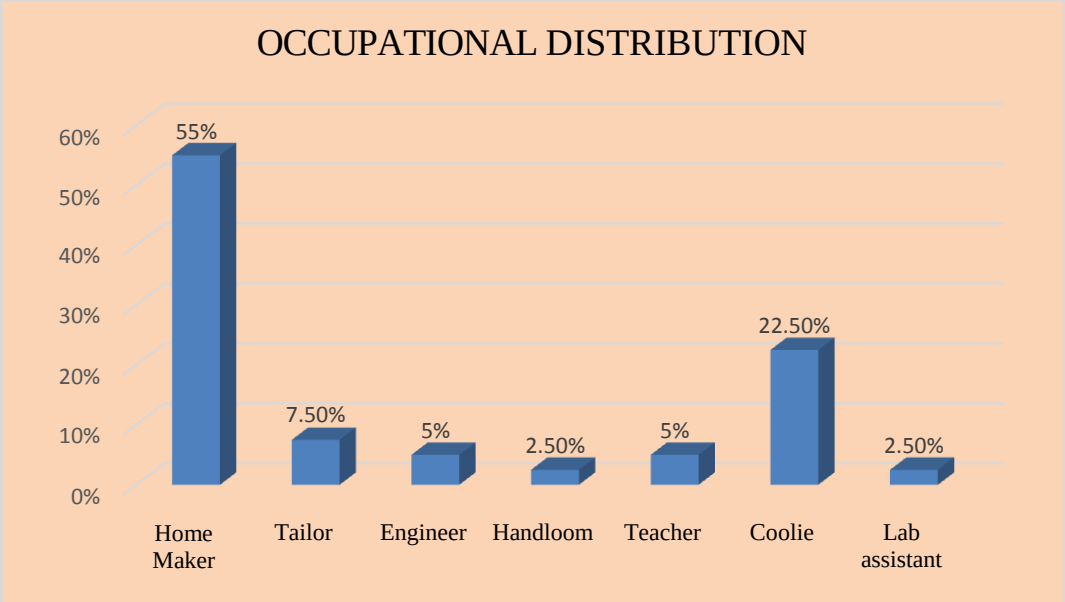


OBSERVATION:

Among 40 patients , 80% were Moderate income, 12.50% were Low income, 7.5% were High income group

4.OCCUPATIONAL DISTRIBUTIONS :

Sl. No	Nature of Work	No. of Cases	Percentage
1	Home Maker	22	55%
2	Tailor	3	7.5%
3	Engineer	2	5%
4	Handloom weavers	1	2.5%
5	Teacher	2	5%
6	Coolie	9	22.5%
7	Lab assistant	1	2.5%

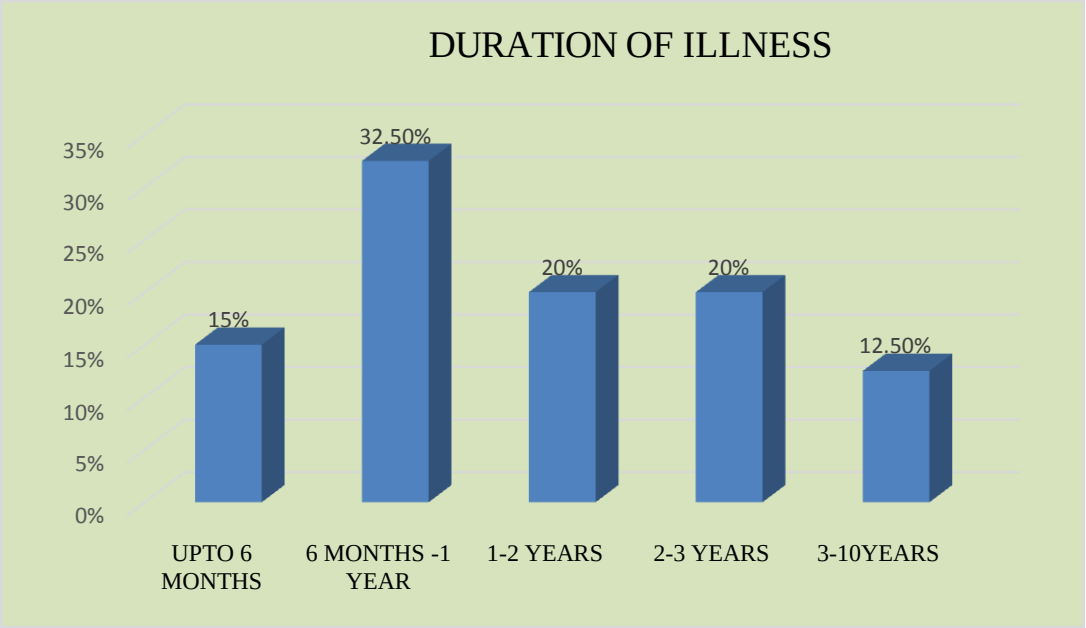


OBSERVATION:

Among 40 cases (55%) were home makers, (7.5%) were tailors, (2.5%) were handloom workers and lab assistant and (22.5%) of them were coolie.

5.DURATION OF ILLNESS:

S.no	Duration of illness	No of cases	Percentage
1	Upto 6 months	6	15%
2	6 months – 1 year	13	32.5%
3	1-2 years	8	20%
4	2-3 years	8	20%
5	3-10 years	5	12.5%

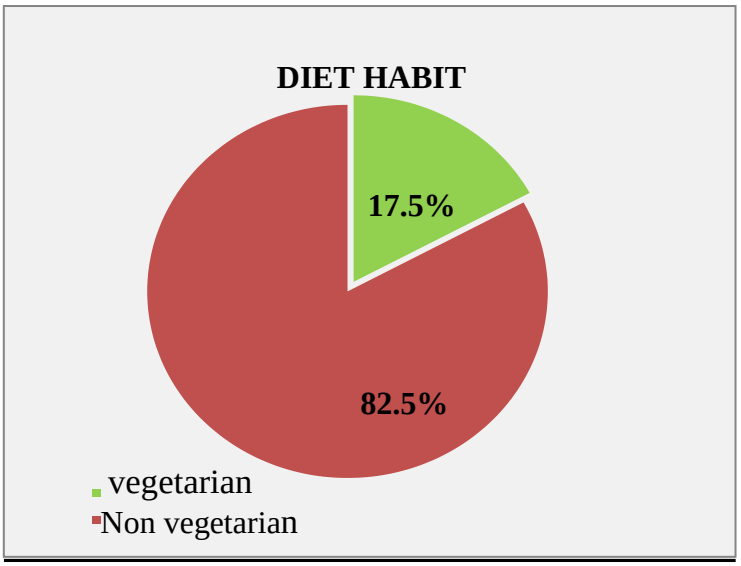


OBSERVATION:

In this study about 12.5% of cases had 3-10yrs of duration, 20% of cases had 2- 3yrs of duration, 20% of cases had 1-2yrs of duration, 32.5% of cases had 6 months-1yr of duration and 15% cases had 6 month of Duration of illness.

6.DIET :

Sl. No	Dietary Habits	No of Cases	Percentage
1	Vegetarian	7	17.5%
2	Non Vegetarian	33	82.5%

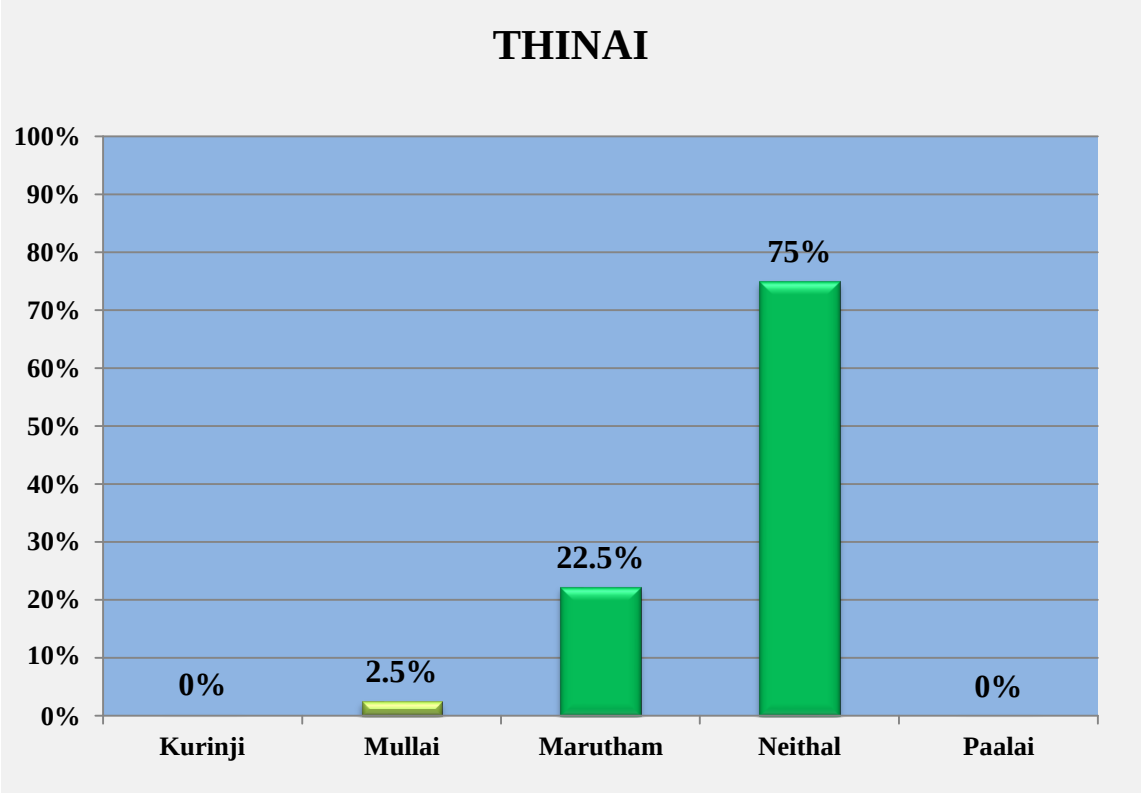


OBSERVATION:

Among 40 patients, 82.5% of patients were non vegetarian and 17.5% of patients were vegetarian.

7.THINAI :

Sl. No	Thinai	No. of Cases	Percentage
1	Kurinji	0	0%
2	Mullai	1	2.5%
3	Marutham	9	22.5%
4	Neithal	30	75%
5	Paalai	0	0%

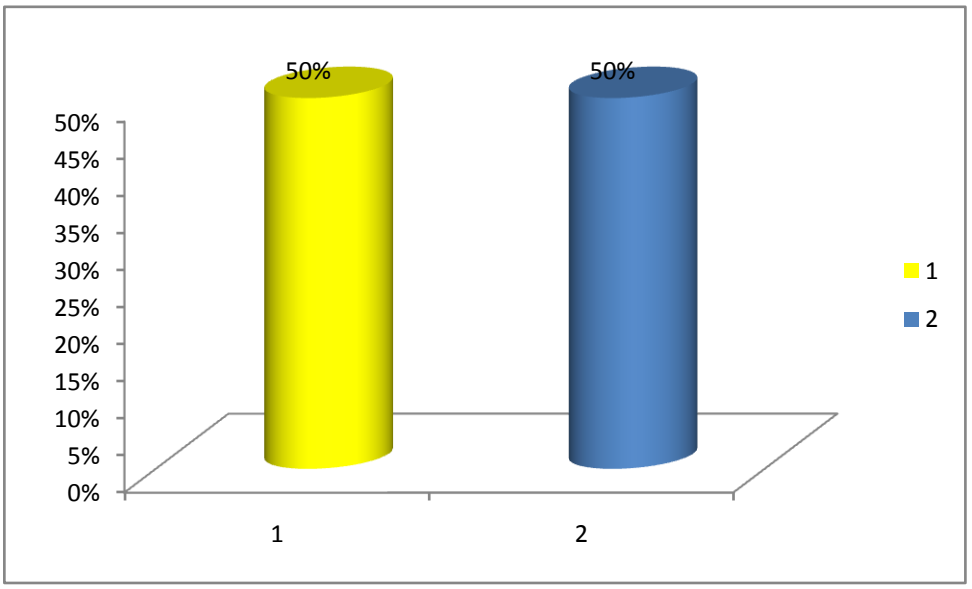


OBSERVATION:

75% of the patients were from Neithal and the remaining (22.5%) from Marutham ,2.5% from Mullai.

8. DISRTIBUTION PARUVAKAALAM

S.NO	PARUVA KAALAM	NO. OF CASES	PERCENTAGE(%)
1.	Kaarkaalam (Aug 18-Oct 17)	0	0
2.	Koothirkaalam (Oct 18-Dec 16)	20	50%
3.	Munpanikaalam (Dec17-Feb 12)	20	50%
4.	Pinpanikaalam (Feb 13-Apr13)	0	0
5.	Elavenilkaalam (Apr 14-Jun 14)	0	0
6.	Muthuvenilkaalam (Jun 15-Aug 17)	0	0

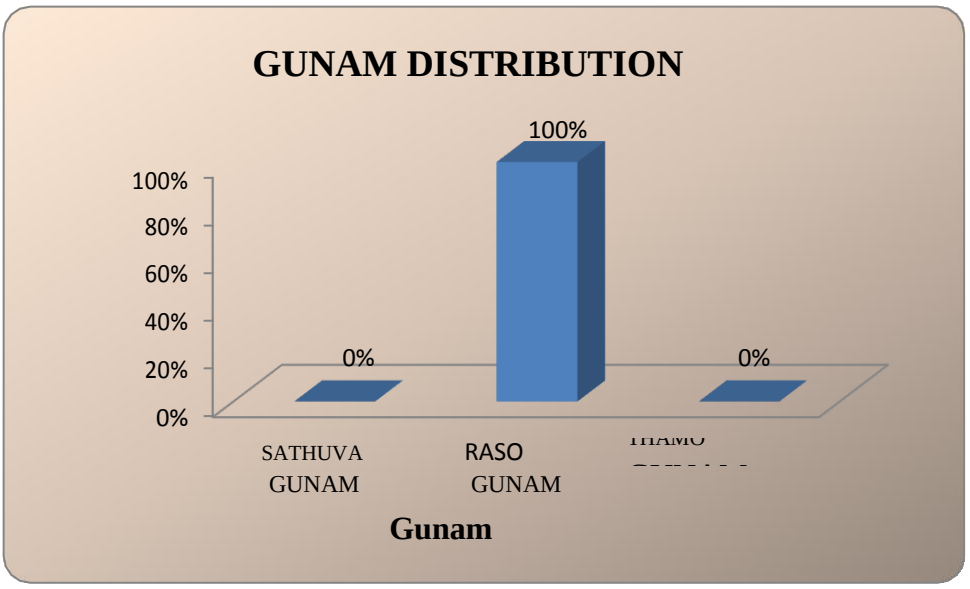


OBSERVATION:

Among 40 cases, 50% (20) of the cases were affected in Koothirkaalam (Oct 18-Dec 16) and other 50% (20) of the cases were affected in Munpanikaalam (Dec17 - Feb 12).

9.GUNAM :

Sl. No	*Gunam*	No of Cases	Percentage
1	Sathuva Gunam	0	0%
2	Raso Gunam	40	100%
3	Thamo Gunam	0	0%

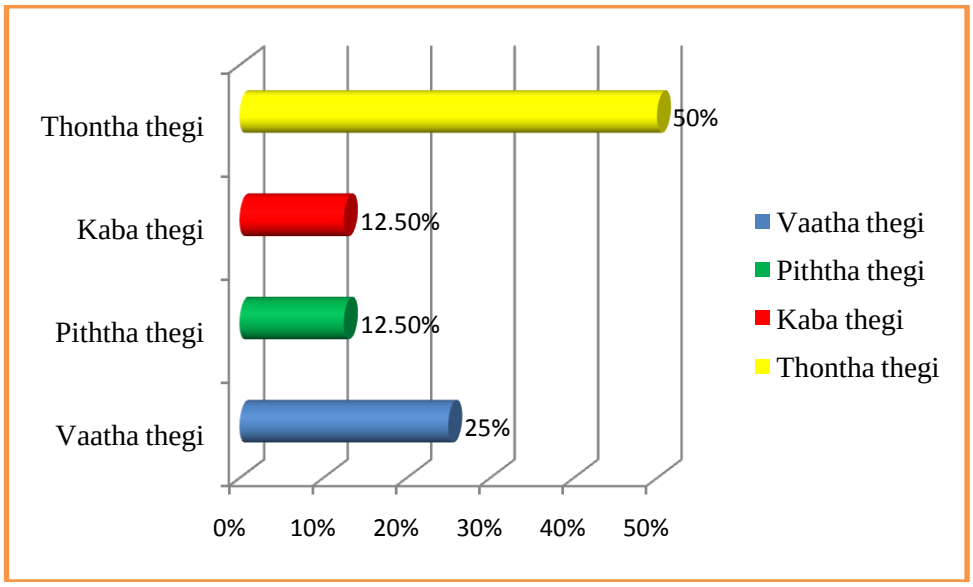


OBSERVATION:

In Gunam 100% of cases had Rasogunam.

10.YAAKAI ILAKKANAM (BODY CONSTITUTION) :

S.no	Yaakaiilak kanam	No of cases	Percentage
1	Vaathathegi	10	25%
2	Pithathegi	5	12.5%
3	Kabathegi	5	12.5%
4	Thonthathegi	20	50%

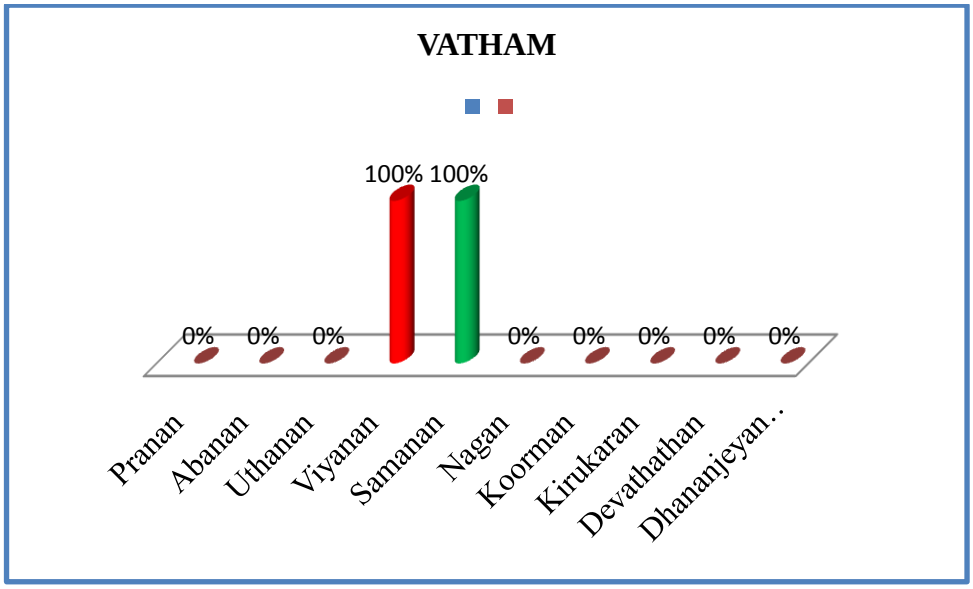


OBSERVATION:

Out of 50%cases were under Thonthaudal, 25% cases wera Vaatha thegi,12.5% cases were Pitha thegi and, 12.5% cases were Kaba thegi .

11.A.DISTRIBUTION OF VAATHAM: BEFORE TREATMENT

S.no	Vaatham	No of cases	Percentage
1	Pranan	-	-
2	Abanan	-	-
3	Uthanan	-	-
4	Viyanan	40	100%
5	Samanan	40	100%
6	Nagan	-	-
7	Koorman	-	-
8	Kirugaran	-	-
9	Devathathan	-	-
10	Dhananjeyan	-	-

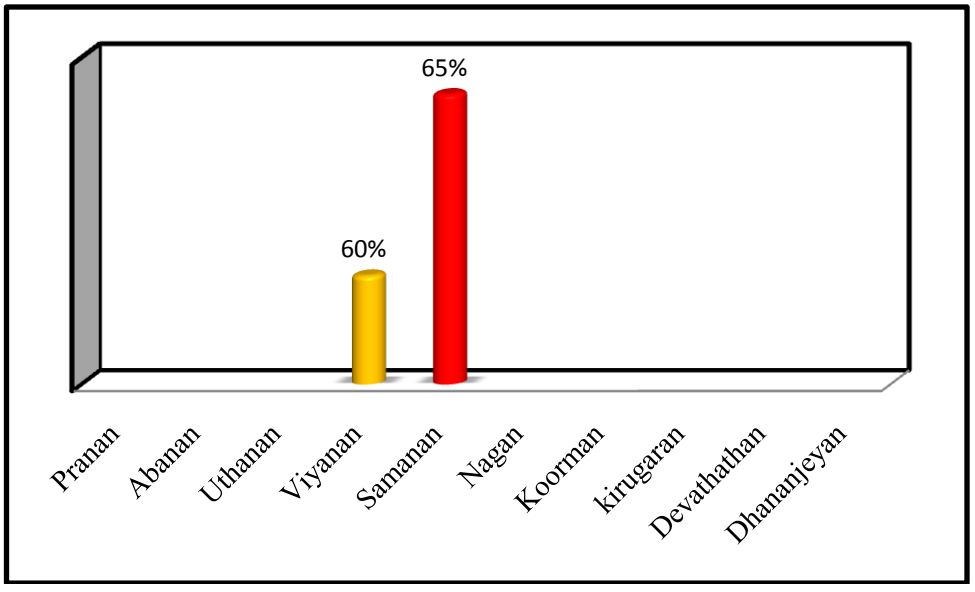


OBSERVATION:

In Vaatham, Viyaanan and Samanan were affected in all 40 cases (100%)

11.B . DISTRIBUTION OF VAATHAM: AFTER TREATMENT

S.no	Vaatham	No of cases	Percentage
1	Pranan	-	-
2	Abanan	-	-
3	Uthanan	-	-
4	Viyanan	24	60%
5	Samanan	26	65%
6	Nagan	-	-
7	Koorman	-	-
8	Kirugaran	-	-
9	Devathathan	-	-
10	Dhananjeyan	-	-

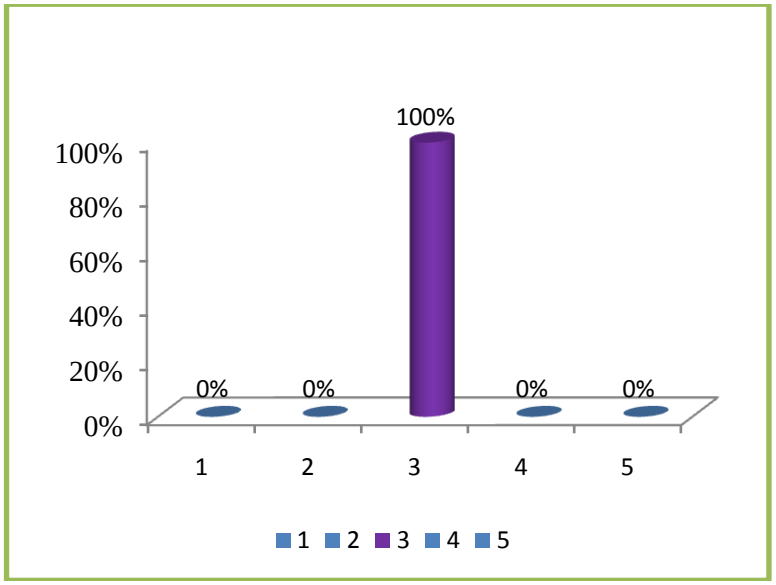


OBSERVATION:

In Vaatham, Viyaanan were affected in 60% of cases, and Samanan were affected in 65% of cases.

12.A. DISTRIBUTION OF PITHAM: BEFORE TREATMENT

S.no	Pitham	No of cases	Percentage
1	Anarpitham	-	-
2	Ranjagapitham	-	-
3	Sathagapitham	40	100%
4	Alosagapitham	-	-
5	Prasagapitham	-	-

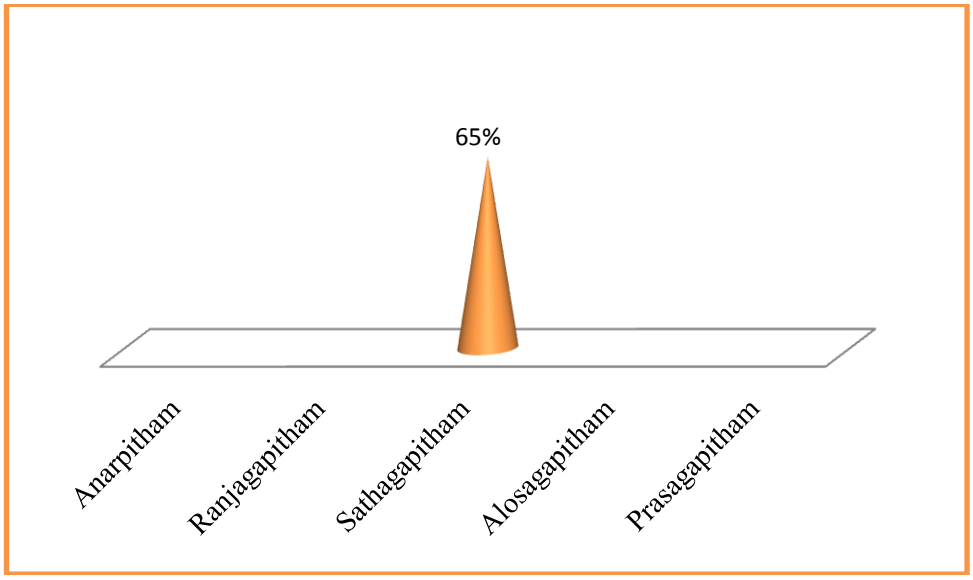


OBSERVATION:

In Pitham, Saathagam was affected in 40 (100%) cases.

12.B. DISTRIBUTION OF PITHAM: AFTER TREATMENT

S.no	Pitham	No of cases	Percentage
1	Anarpitham	-	-
2	Ranjagapitham	-	-
3	Sathagapitham	26	65%
4	Alosagapitham	-	-
5	Prasagapitham	-	-

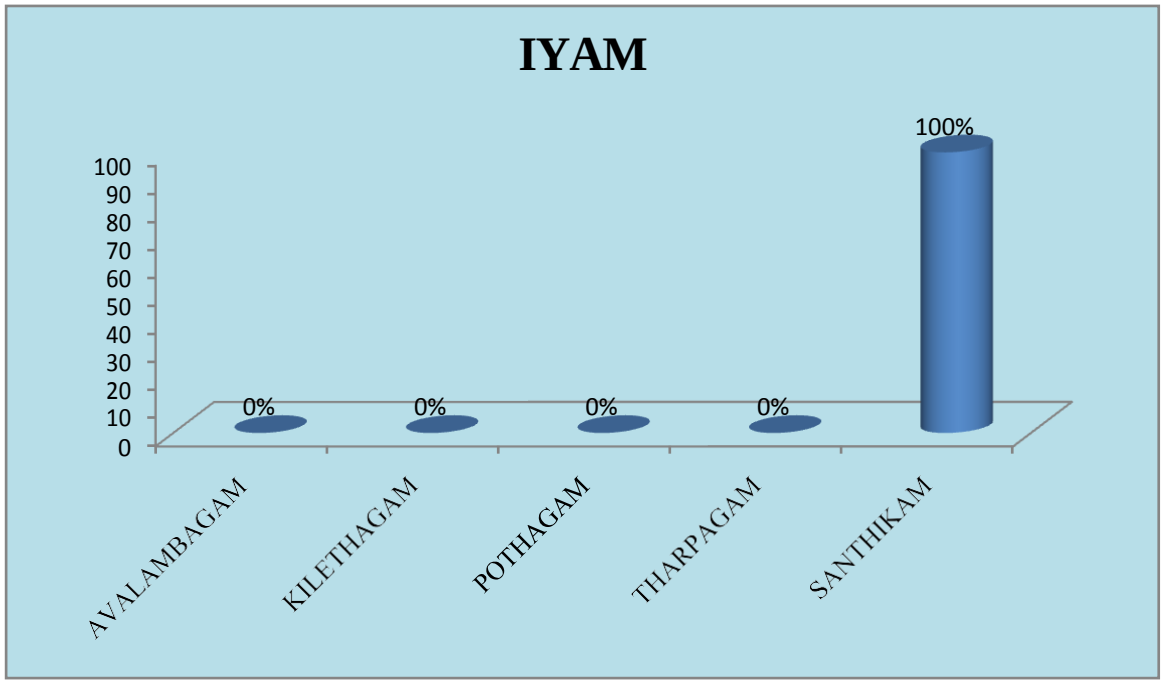


OBSERVATION:

In Pitham, Saathagam was affected in 26(65%) cases.

13. A.DISTRIBUTION OF IYYAM : AFTER TREATMENT

S.no	Iyyam	No of cases	Percentage
1	Avalambagam	-	-
2	Kilethagam	-	-
3	Pothagam	-	-
4	Tharpagam	-	-
5	Santhigam	40	100%

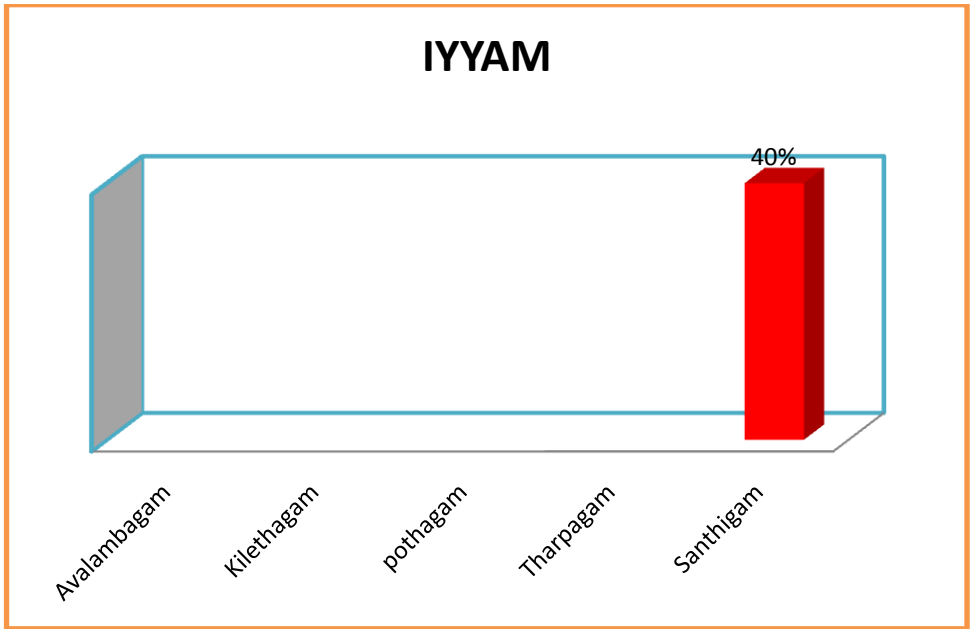


OBSERVATION:

In Iyam, santhigam was affected in all cases(100%).

13.B. DISTRIBUTION OF IYYAM :AFTER TREATMENT

S.no	Iyyam	No of cases	Percentage
1	Avalambagam	-	-
2	Kilethagam	-	-
3	Pothagam	-	-
4	Tharpagam	-	-
5	Santhigam	16	40%

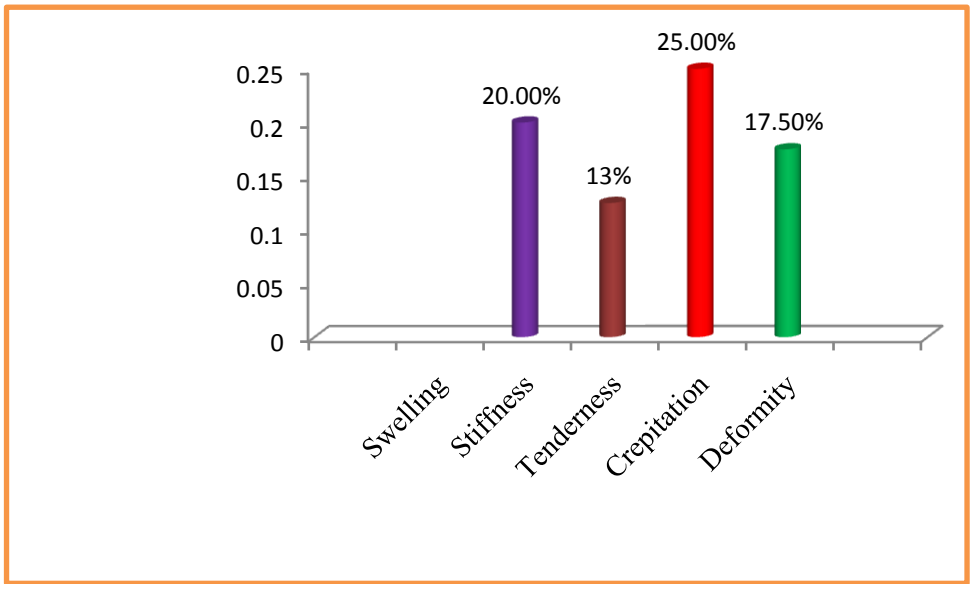


OBSERVATION:

In Iyam, santhigam was affected in 16 cases (40%).

14.A. CLINICAL FEATURES: Before Treatment

Sl. No	Clinical Features	No of Cases	Percentage
	Swelling	40	100%
2	Stiffness	29	72.5%
3	Tenderness	14	35%
4	Crepitation	37	92.5%
5	Deformity	7	12.5%

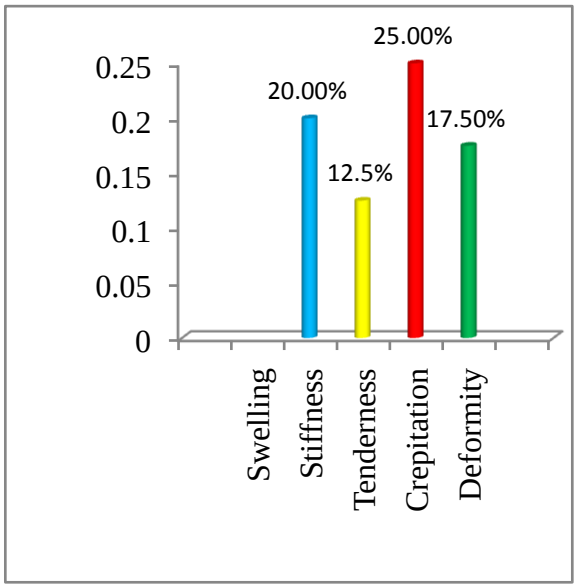


OBSERVATION:

In this study, all 100% of cases had Swelling, 72.5% of cases had Stiffness, 35% of cases had Tenderness, 92.5% of cases had crepitations, and 12.5% of cases had Deformity.

14.B. CLINICAL FEATURES: After Treatment

Sl. No	Clinical Features	No of Cases	Percentage
1	Swelling	9	22.50%
2	Stiffness	8	20%
3	Tenderness	5	12.5%
4	Crepitation	10	25%
5	Deformity	7	17.5%



OBSERVATION:

In this study, 22.5% of cases had Swelling, 20% of cases had Stiffness, 25% of cases had crepitations, 17.5% of cases had Deformity, and 12.5% cases had Tenderness.

15A. ENVAGAI THERVUGAL: BEFORE TREATMENT:BEFORE TREATMENT

Sl. No	EnvagaiThervugal	No. of Cases	Percentage
1	Naadi		
	a. Vathapiththam	20	50%
	b. Piththavatham	10	25%
	c. Kabavatham	4	10%
	d. Kabapiththam	-	-
2	Sparisam	-	-
3	Naa	-	-
4	Niram	-	-
5	Mozhi	-	-
6	Vizhi	-	-
7	Malam	-	-
8	Moothiram	-	-

OBSERVATION:

The Naadinadai seen in *Azhal Keel Vaayu* patients were Vathapitham 50%, Pithavatham 25 %, Kabavatham .

15.B.ENVAGAI THERVUGAL: AFTER TREATMENT:AFTER TREATMENT

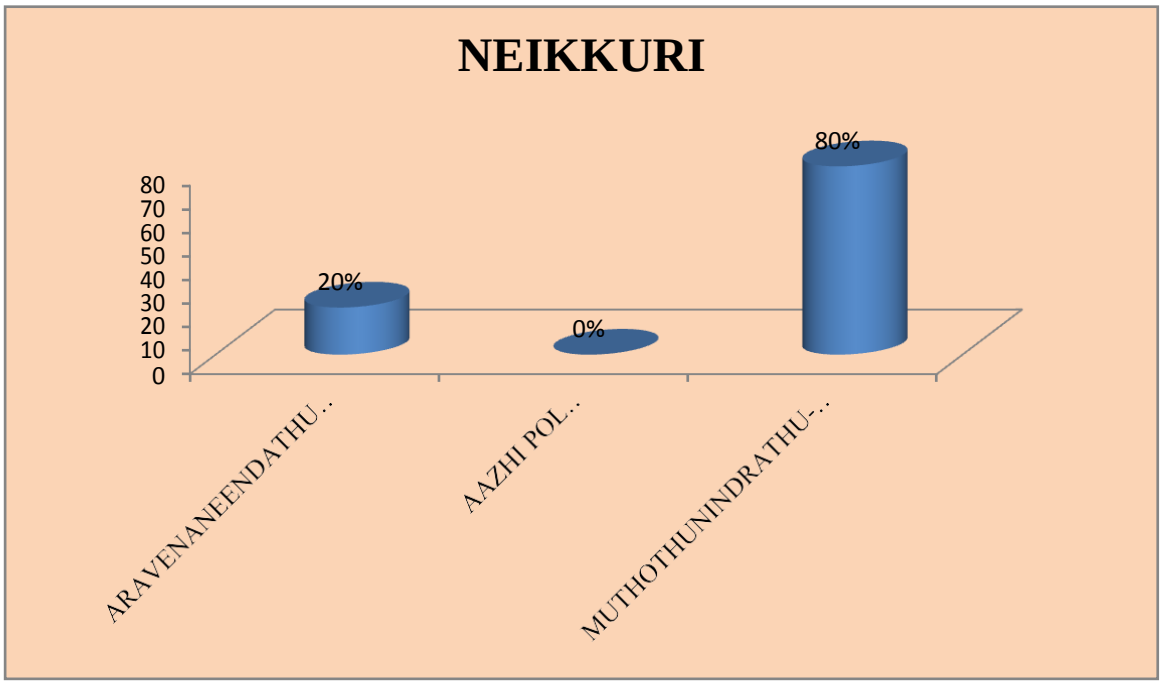
Sl. No	EnvagaiThervugal	No. of Cases	Percentage
1	Naadi		
	a. Vathapiththam	18	45%
	b. Piththavatham	12	30%
	c. Kabavatham	3	7.5%
	d. Kabapiththam	-	
2	Sparisam	-	-
3	Naa	-	-
4	Niram	-	-
5	Mozhi	-	-
6	Vizhi	-	-
7	Malam	-	-
8	Moothiram	-	-

OBSERVATION:

The Naadinadai seen in *Azhal Keel Vaayu* patients were Vathapitham 45%, Pithavatham 30 %, Kabavatham 7.5% .

16.A. NEIKKURI: BEFORE TREATMENT

S.no	Neikuri	No of cases	Percentage
1	Vaatha neer (Aravenaneendathu)	8	20%
2	Pithaneer (Aazhipolparaviyathu)	-	-
3	Kaba neer (Muthothuninrathu)	32	80%
4	Others	-	-

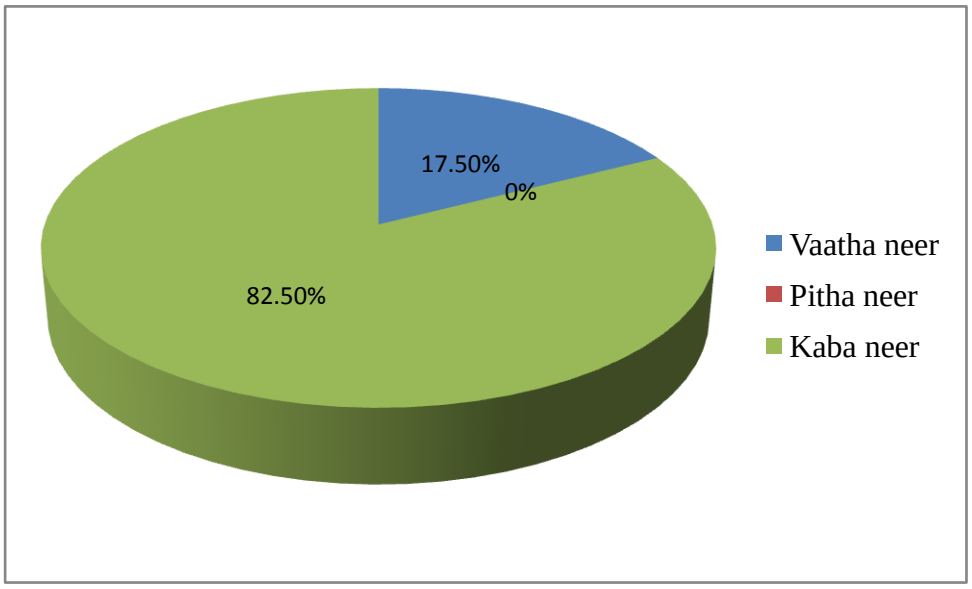


OBSERVATION:

Among 40 cases, Vaatha neer was found in 8 cases (20%) and Kaba neer was found in 32 cases (80%).

16.B.NEIKURI: AFTER TREATMENT

S.No	Neikuri	No of cases	Percentage
1	Vaatha neer (Aravenaneendathu)	7	17.5%
2	Pithaneer (Aazhipolparaviyathu)	-	-
3	Kaba neer (Muthothuninrathu)	33	82.5%
4	Others	-	-

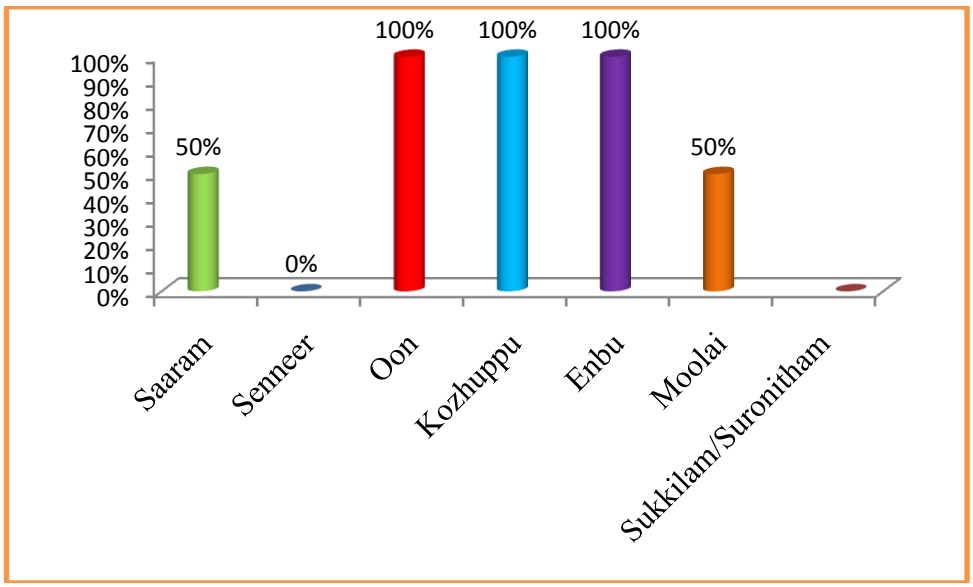


OBSERVATION:

Among 40 cases, Vaatha neer was in (17.5%) and Kaba neer was found in 82.5%.

17.A.UDAL THAATHUKKAL : BEFORE TREATMENT

S.no	Udalthaathukkal	No of cases	Percentage
1	Saaram	20	50%
2	Senneer	-	-
3	Oon	40	100%
4	Kozhuppu	40	100%
5	Enbu	40	100%
6	Moolai	20	50%
7	Sukkilam/Suronitham	-	-

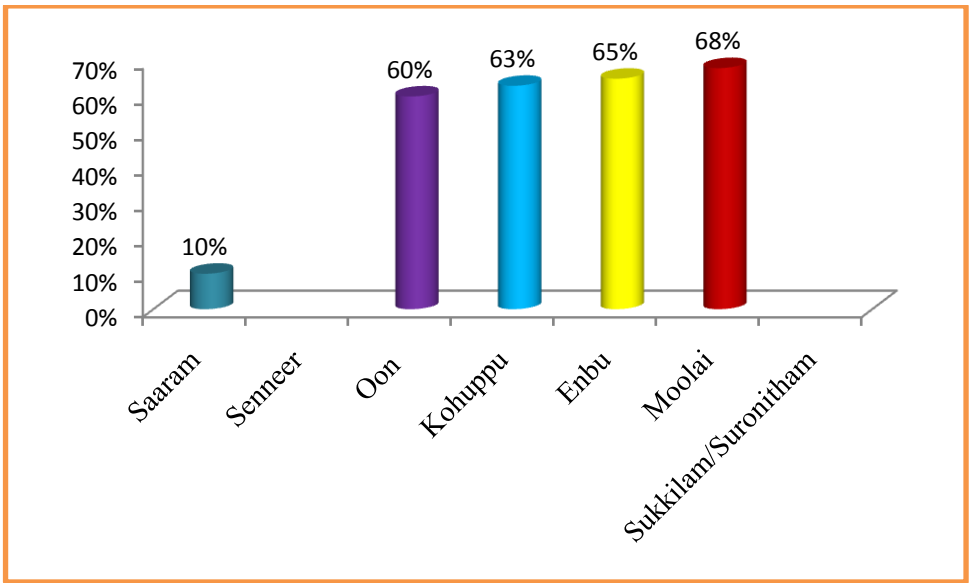


OBSERVATION:

In this study Saaram were affected in50%, Oon, Kozhuppu and Enbu were affected in all 40cases (100%). Moolai was affected in 20 cases (50%).

17. B.UDAL THAATHUKKAL :AFTER TREATMENT

S.no	Udalthaathukkal	No of cases	Percentage
1	Saaram	20	10%
2	Senneer	-	-
3	Oon	40	60%
4	Kozhuppu	40	63%
5	Enbu	40	65%
6	Moolai	20	68%
7	Sukkilam/Suronitham	-	-

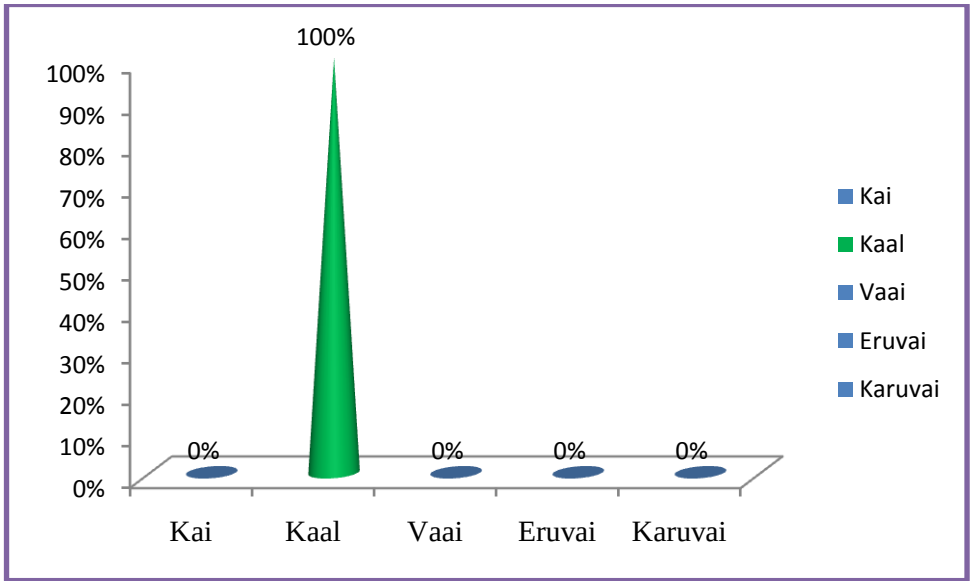


OBSERVATION:

In this study Saaram, Oon and Enbu were affected in all 40cases (100%). Kozhuppu was affected in 20 cases (50%).

18.A.KANMENTHIRIYAM : BEFORE TREATMENT

S.no	Kanmenthiriyam	No of cases	Percentage
1	Kai	-	-
2	Kaal	40	100%
3	Vaai	-	-
4	Eruvai	-	-
5	Karuvai	-	-

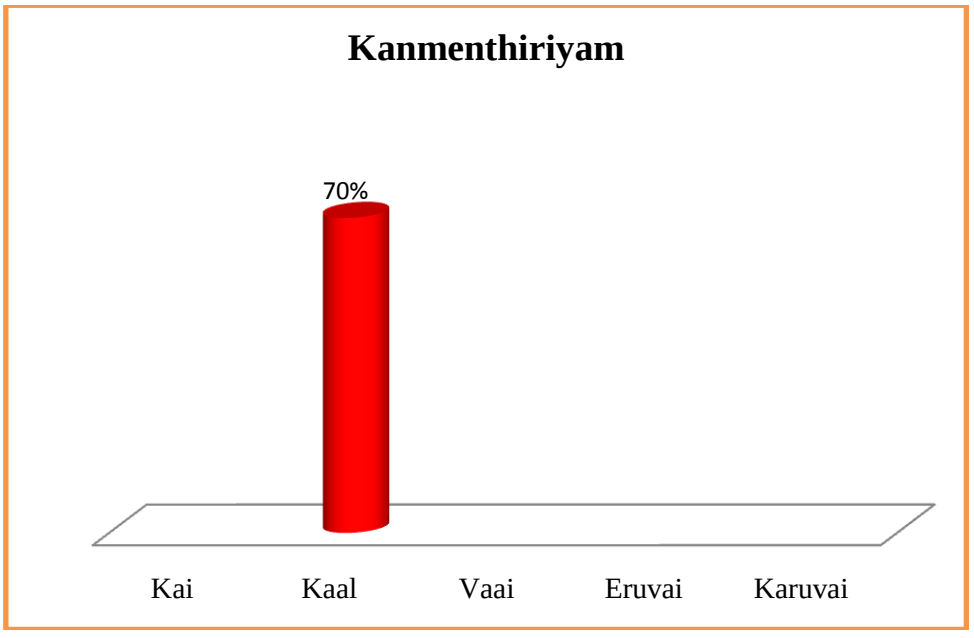


OBSERVATION:

In Kanmenthiriym, Kaal were affected in all 40 cases .

18.B.KANMENTHIRIYAM :

S.no	Kanmenthiriyam	No of cases	Percentage
1	Kai	-	-
2	Kaal	28	70%
3	Vaai	-	-
4	Eruvai	-	-
5	Karuvai	-	-



OBSERVATION:

In Kanmenthiriym, Kaal were affected in 29 cases .

VARMAM MANIPULATION RESULTS ACCORDING TO PAIN SCALE

OPD CASES CLINICAL IMPROVEMENT (PAIN SCORE)

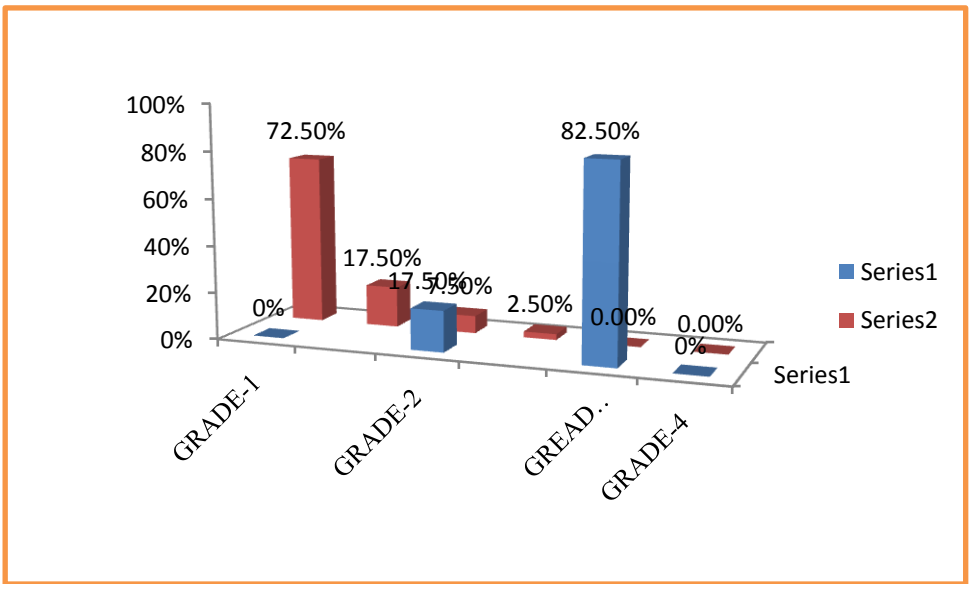
S.No	OP No	NAME	AGE/ SEX	PAIN SCORE		ROMS	
				BT	AT	BT	AT
1.	K 95654	RAMA	40/F	8	1	G3	G1
2.	F 006953	JEYANTHI	36/F	7	1	G3	G1
3.	L 10676	RAVI	55/M	7	1	G3	G1
4.	L 10014	D.MANIMEGALAI	48/F	6	4	G3	G2
5.	K 61602	ELUMALAI	54/M	7	0	G3	G1
6.	H 33143	GUNASUNDARI	44/F	6	1	G2	G1
7.	I 68290	SHANTHI	55/F	6	1	G2	G1
8.	I 20367	MALARKODI	44/F	7	2	G3	G1
9.	J 13408	JAMUNA	56/F	8	3	G3	G2
10.	L16992	LAKSHIMI	38/F	8	1	G3	G1
11.	K 82380	KAMALAKANNAN	54/M	8	2	G3	G1
12.	K 97879	RAMESH	52/M	8	1	G3	G1
13.	J 33561	RANI	64/F	8	1	G3	G1
14.	G 452488	SAVITHRI	62/F	8	6	G3	G1
15.	L17157	SENTHAMARAI	46/F	8	3	G3	G1
16.	J43232	DEIVANAI	51/F	8	1	G3	G1
17.	J84340	RAJENDRAN	57/M	7	2	G3	G1
18.	L00048	MANIMEGALAI	63/F	7	0	G3	G1
19.	L19986	MARIYA VICTORIYA	50/F	6	3	G2	G1
20.	K60567	PRABHU	42/M	7	2	G3	G1

PAIN SCORE BEFORE AND AFTER TREATMENT: TRAIL DRUG

S.No	OP No	NAME	AGE/ SEX	PAIN SCORE		ROMS	
				BT	AT	BT	AT
21	I42030	RAJESHWARI	55/F	8	6	G3	G3
22	K98073	KAVIARASI	50/F	7	3	G3	G1
23	I58783	BHANUMATHI	60/F	7	1	G3	G1
24	J44324	CHANDRA	54/F	8	1	G3	G1
25	J97399	ANNA PUSHPAM	62/F	6	1	G2	G1
26	L03219	GEETHA	53/F	6	4	G3	G2
27	J47444	JAWAHAR	57/M	8	1	G3	G1
28	K60568	RAMYA	39/F	8	1	G3	G1
29	K5308	JAYA	63/F	4	3	G3	G1
30	G58335	RAJESH METHA	51/M	7	1	G3	G1
31	1779-18	REVATHI	48/F	6	2	G3	G1
32	1774-18	VASANTHA	57/F	8	0	G3	G1
33	K19651	VIJAYAKUMAR	45/M	6	3	G2	G1
34	H83252	SUBULAKSHMI	63/F	6	1	G2	G1
35	K47168	KANCHANA	52/F	7	2	G3	G1
36	G90503	SELVAM	47/M	8	1	G3	G1
37	H25390	ANITHA	45/F	8	1	G3	G1
38	F75898	SUMATHI	56/F	7	2	G3	G1
39	H09508	SARASU	61/F	8	1	G3	G1
40	L01690	RANI	45/F	7	1	G2	G11

19. OUTCOME MEASURESRESTRICTED MOVEMENT ASSESMENT SCALE:

GRADING	BEFORE TREATMENT		AFTER TREATMENT		
	Number of Patients	Percentage %	GRADING	Number Patients	Percentage %
GRADE I	0	0%	G3-G1	29	72.5%
			G2-G1	7	17.5%
GRADE II	7	17.5%	G3-G2	3	7.5%
			G2-G2	1	2.5%
GRADE III	33	82.5%			
GRADE IV	0	0%			
GRADE V	0	0%			
TOTAL	**40**	**100%**		**40**	**100%**

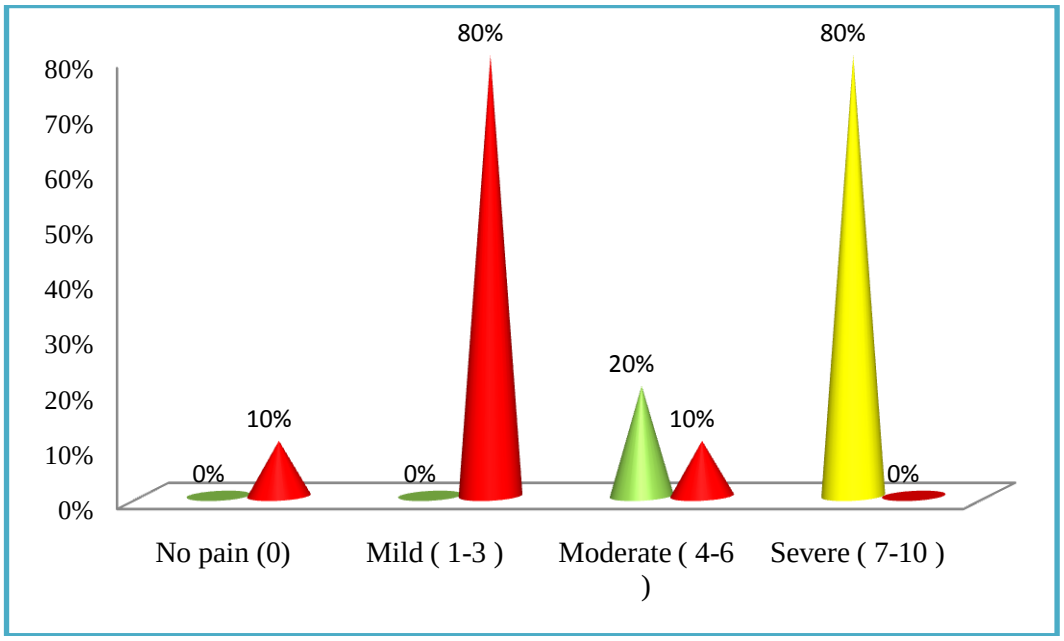


OBSERVATION:

After the treatment among 40 patients were observed in (72.5%) ,(17.5%) Grade 1, (35%), and (7.5%)(,2.5%)of cases were Grade 2.

20.A.PAIN ASSESSMENT (VARMAM + TRIAL DRUG) Group A :

Pain assessment (varmam + trial drug)	BEFORE TREATMENT		AFTER TREATMENT	
	Number of Patients	Percentage %	Number of Patients	Percentage %
No pain (0)	0	0%	2	10%
Mild (1-3)	0	0%	16	80%
Moderate(4-6)	4	20%	2	10%
Severe(7-10)	16	80%	0	0%
Total	20	100%	20	100%

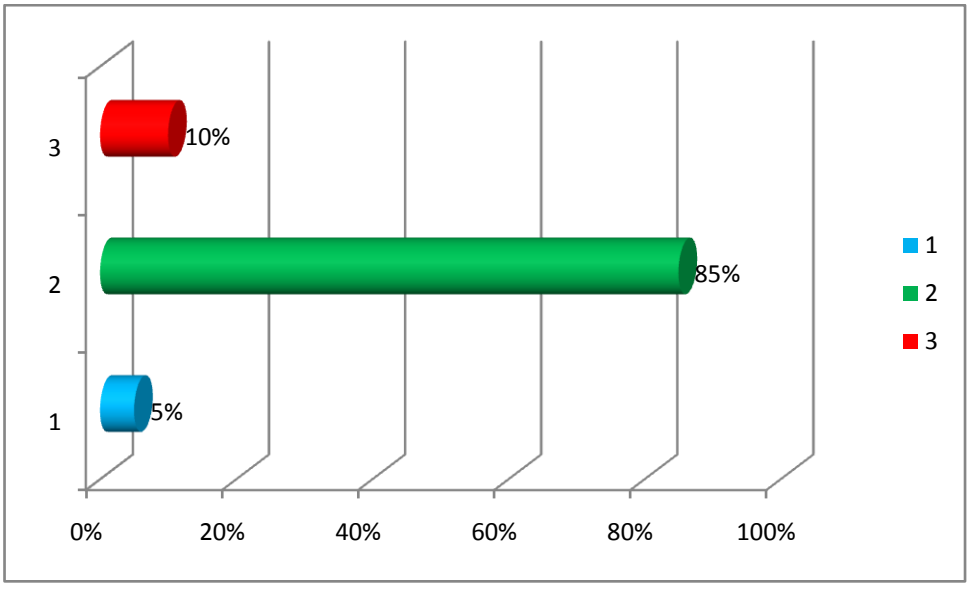


OBSERVATION:

In this study (80%) of cases had mild pain, (10%) of cases had modrate pain and (10%) of cases no pain.

20. B.PAIN ASSESSMENT (TRIAL DRUG ONLY) Group B:

Pain assessment (trial drug only)	BEFORE TREATMENT		AFTER TREATMENT	
	Number of Patients	Percentage %	Number of patients	Percentage %
No pain 0	0	0%	1	5%
Mild (1-3)	0	0%	17	85%
Moderate (4-6)	6	30%	2	10%
Severe(7-10)	14	70%	0	0%
Total	20	100%	20	100%

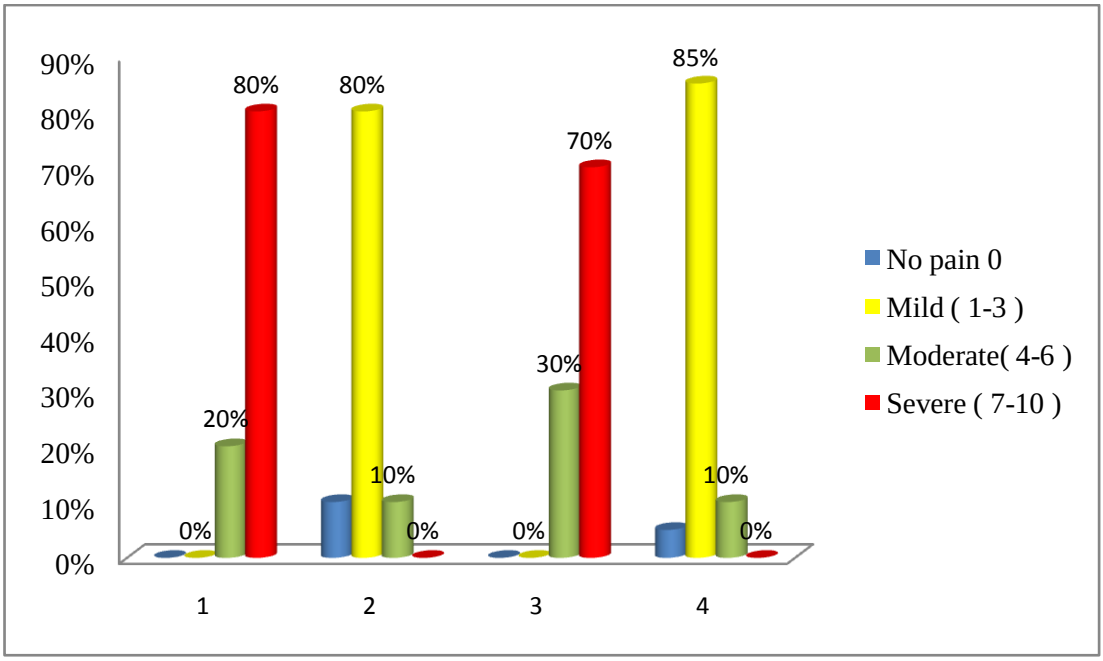


OBSERVATION:

Among the 20 cases, after the treatment the pain was reduced in 20 cases (50%), mild pain was present in 17 cases (85%)moderate pain was present in 2case(10%%), and no pain was present in 5%.

21.PAIN ASSESSMENT:

PAIN ASSESSMENT	VARMAM + TRIAL DRUG				TRIAL DRUG			
	Before Treatment		After Treatment		Before Treatment		After Treatment	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
No pain 0	0	0%	2	10%	0	0%	1	5%
Mild (1-3)	0	0%	16	80%	0	0%	17	85%
Moderate(4-6)	4	20%	2	10%	6	30%	2	10%
Severe (7-10)	16	80%	0	0%	14	70%	0	0%
Total	20	100%	20	100%	20	100%	20	100%

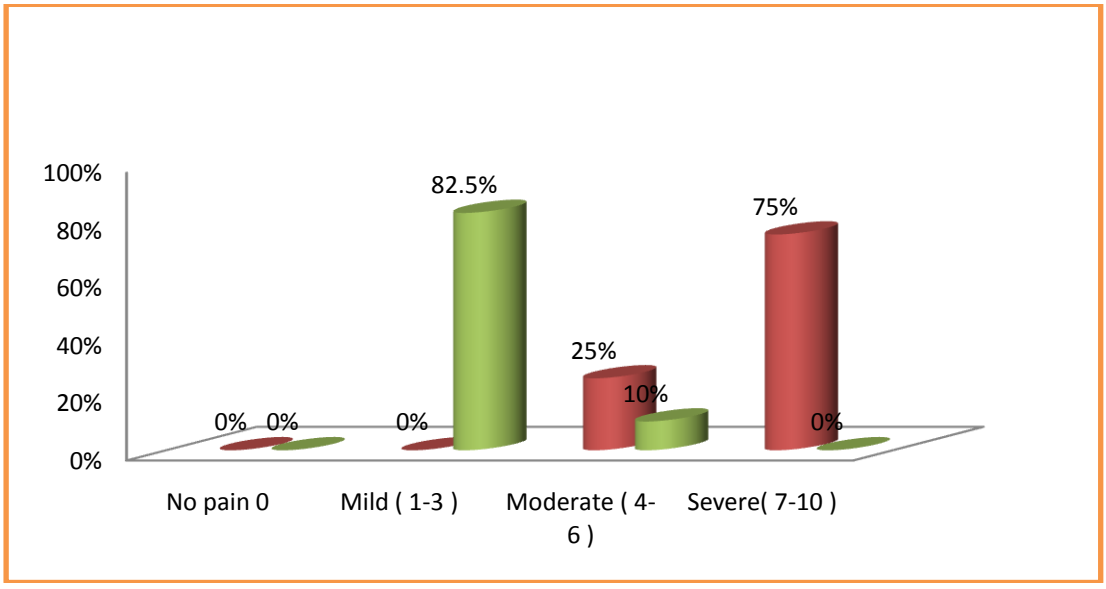


OBSERVATION:

Among 40 patients, in varmam trial drug after the treatment about 85% of the patients have mild pain, 10% of patients have moderate pain and 5% of patients had no pain.

22.PAIN ASSESMENT SCALE

Pain assessment (trial drug only)	BEFORE TREATMENT		AFTER TREATMENT	
	Number of Patients	Percentage %	Number of Patients	Percentage %
No pain 0	0	0%	3	7.5%
Mild (1-3)	0	0%	30	82.5%
Moderate (4-6)	10	25%	7	10%
Severe(7-10)	30	75%	0	0%
Total	40	100%	20	100%

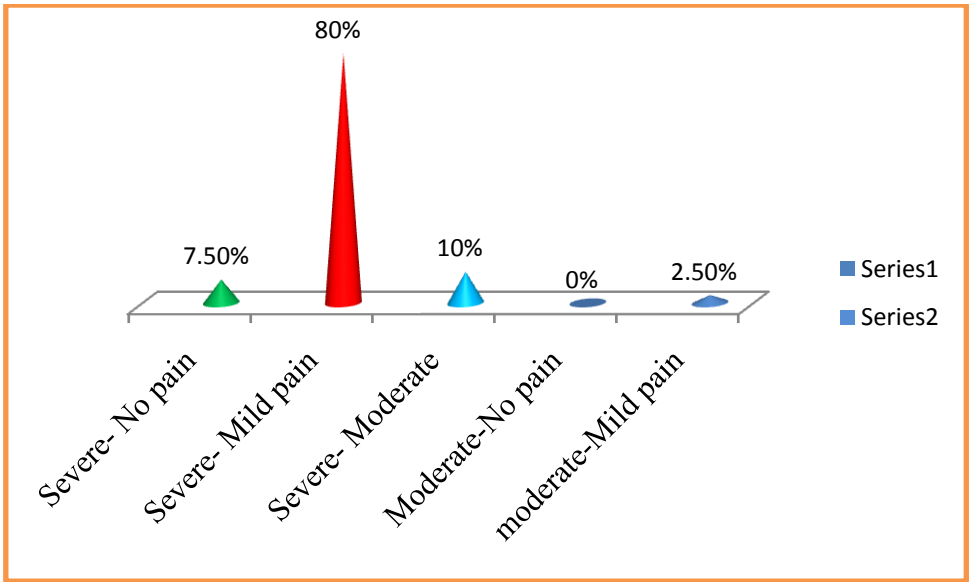


OBSERVATION:

Among 40 patients, after the treatment, no pain was found in (7.5%), mild pain was found in (82.5%), and moderate pain was found in (10%).

23.RESULTS :

RESULT	NUMBER OF CASES	PERCENTAGE
Severe -No pain	3.00	7.5%
Severe-Mild pain	32	80%%
Severe-Moderate pain	4	10.0%
Moderate-No pain	0	0%
Moderate-Mild pain	1	2.5%
Total	**40**	**100%**



OBSERVATION:

Out of 40 cases, Severe-No pain were obserbed in 7.5%,Severe- Mild pain was observed in 80%, Severe-Moderate pain was observed in 10%,Moderate-Mild pain was observed in 2.5%

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

S. NO.	OP NO	NAME	Hb gm%		TRBC Million/cumm	
			BT	AT	BT	AT
1	K 95654	RAMA	12.9	13.6	4.1	4.4
2	F 006953	JEYANTHI	11.4	10.5	4.4	4.0
3	L 10676	RAVI	16.00	16.5	4.6	4.9
4	L 10014	D.MANIMEGALAI	12.4	11.7	4.5	4.3
5	K 61602	ELUMALAI	13.9	13.9	4.6	4.6
6	H 33143	GUNASUNDARI	13.1	12.8	4.5	4.4
7	I 68290	SHANTHI	13.5	14.9	4.4	5.3
8	I 20367	MALARKODI	11.4	10.4	3.9	3.6
9	J 13408	JAMUNA	12.7	12.6	4.4	4.3
10	L16992	LAKSHIMI	13.2	13.8	4.4	4.7
11	K 82380	KAMALAKANNAN	15.4	15.0	4.5	4.5
12	K 97879	RAMESH	15.5	15.3	5.2	5.2
13	J 33561	RANI	12.6	13.2	4.4	4.5
14	G452488	SAVITHRI	11.3	11.7	3.8	3.9
15	L17157	SENTHAMARAI	8.7	10.2	4.6	4.5
16	J43232	DEIVANAI	14.9	15.4	4.9	5.1
17	J84340	RAJENDRAN	11.2	11.4	4.3	4.5
18	L00048	R.MANIMEGALAI	13.7	13.6	4.8	4.8
19	L19986	MARIYA VICTORIYA	12.3	12.7	4.0	4.3
20	K60567	PRABHU	15.00	15.4	4.9	5.1

SL.NO	OP NO	NAME	Hb gm%		TRBC Million/cumm	
			Before Treatment	After treatment	Before treatment	After Treatment
21	I42030	RAJESHWARI	12.1	12.9	4.6	4.2
22	K98073	KAVIARASI	11.9	12.3	5.1	5.5
23	I58783	BHANUMATHI	11.4	14.1	4.5	4.4
24	J44324	CHANDRA	13.1	13.4	5.3	4.5
25	J97399	ANNA PUSHPAM	12.7	12.6	4.4	4.3
26	L03219	GEETHA	12.3	11.9	5.3	5
27	J47444	JAWAHAR	15.5	15.3	4.9	4.8
28	K60568	RAMYA	13.7	11.6	5.1	5.2
29	K5308	JAYA	13.5	14.9	5	5
30	G58335	RAJESH METHA	16.1	16.3	5.4	5.2
31	1779-18	REVATHI	11.9	14.4	4.2	5.3
32	1774-18	VASANTHA	10.2	13.3	4.8	4.6
33	K19651	VIJAYAKUMAR	12.1	12.7	5.1	5.2
34	H83252	SUBULAKSHMI	13.4	13.5	5	5.1
35	K47168	KANCHANA	12.1	13.2	4.3	4.5
36	G90503	SELVAM	11.5	10.9	5	4.7
37	H25390	ANITHA	14.7	13.9	4.5	4.4
38	F75898	SUMATHI	14.8	14.4	5.4	5
39	H09508	SARASU	11.3	12	4.5	4.6
40	L01690	RANI	14.5	14.8	4.9	5.1

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

S.NO	IP NO	T.CHOLESTEROL (mg/dl)		HDL (mg/dl)		LDL (mg/dl)		VLDL (mg/dl)		TGL (mg/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	K 95654	189	216	36	41	105	127	78	75.1	248	243
2	F 006953	209	179	65	59.4	102	93.9	19	13.5	98	67.5
3	L10676	148	147	56	55	70	68.1	13.7	14	68.5	70
4	L 10014	262	258	56	48	143	151	43	74	214	220
5	K 6160	212	230	51	57.7	111	125	12	18.5	63	92.5
6	H 33143	132	147	48	50.6	67	68.1	18	13.1	88	65.4
7	I 68290	261	228	68	86	140	123	12	56	61	64
8	I 20367	201	171	53	42	113	96	31	32	158	159
9	J 13408	212	199	55	53.9	110	128	23	27	107	95
10	L16992	209	228	55	58	106	112	32	36	115	139
11	K82380	186	198	39	37	98	105	42	51	212	254
12	K97879	227	222	49	53	113	121	21	33	107	165
13	J33561	224	215	54	58	116	139	22	36	112	153
14	G45248	173	172	61	70	79	81	12	30	62	80
15	L17157	195	190	42	52	99	90	25	26	125	130
16	J43232	210	195	50	49	105	111	30	39	149	196
17	J84340	194	213	59	59	115	169	23	18.3	101	91.4
18	L00048	218	235	56	53	121	120	27	21	134	107
19	L19986	225	184	60	55	116	113	26	21	128	104
20	K60567	135	147	34	45	70	82	17	37	143	183

S.NO	OP NO	T.CHOLESTEROL (mg/dl)		HDL (mg/dl)		LDL (mg/dl)		VLDL (mg/dl)		TGL (mg/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	I 42030	191	196	53	53	96	99	24	27	118	126
22	K98073	160	165	50	50	77	75	18	20	90	96
23	I58783	193	206	47	52	99	114	28	21	140	103
24	J44324	236	258	58	67	120	146	16	20	80	104
25	J97399	210	237	48	57	117	141	36	31	180	165
26	L03219	172	189	56	66	82	90	21	11	105	58
27	J47444	222	257	54	60	111	132	31	32	156	159
28	K60568	212	119	53	48	108	58	19	20	97	45
29	K5308	196	219	56	60	92	123	19	19	93	95
30	G58335	233	244	47	46	138	133	34	36	173	182
31	1779-18	173	163	46	47	98	101	20	23	99	113
32	1774-18	214	242	58	57	122	118	27	25	135	129
33	K19651	201	210	56	58	108	121	29	35	147	167
34	H83252	228	228	52	48	137	123	21	24	105	123
35	K47168	305	300	77	70	176	170	21	25	103	105
36	G90503	202	178	64	52	110	105	14	31	72	157
37	H25390	224	193	62	45	122	109	64	58	320	290
38	F75898	150	158	50	43	110	89	20	23	102	113
39	H09508	212	201	53	47	108	111	19	20	97	100
40	L06690	213	228	51	57	109	119	15	20	77	102

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

S. N	OP.NO	TC Cells/µL		DC						ESR			
				P		L		Mxd		½ HR		1 HR	
		BT	AT	BT	A T	B T	A T	BT	A T	BT	AT	BT	AT
1	K 95654	7.600	9000	65	69	30	27	05	02	16	32	24	50
2	F 006953	6.000	7000	57	67	39	30	04	03	34	40	24	50
3	L 10676	6.200	5,900	75	75	20	21	05	04	16	32	02	04
4	L 10014	7.600	8200	65	67	33	29	02	02	10	8	22	18
5	K 61602	7.500	7100	79	62	18	35	03	03	10	08	20	16
6	H 33143	6.800	6200	60	65	30	30	10	05	8	12	16	24
7	I 68290	6.100	6300	55	65	42	42	03	02	06	12	18	18
8	I 20367	3.600	3.700	60	65	32	29	08	06	20	30	40	35
9	J 13408	6.900	7.200	55	58	41	38	04	02	30	06	60	12
10	L16992	7.400	7.400	55	53	43	41	03	06	8	20	18	30
11	K 82380	8.200	7.000	65	69	31	27	04	04	4	08	10	18
12	K 97879	6.500	4.700	75	60	22	37	03	03	04	04	08	08
13	J 33561	4.900	5.000	65	65	31	32	04	03	06	08	14	20
14	G45248	4.800	4.900	62	63	34	33	04	03	34	35	50	52
15	L17157	9.000	9.100	75	75	20	21	02	04	14	18	20	30
16	J43232	8.600	9.700	69	73	28	24	03	03	16	24	34	50
17	J84340	6.600	6.600	65	64	30	32	05	03	8	10	0	20
18	L00048	9.500	8.500	68	69	26	27	05	05	20	60	40	30
19	L19986	6.400	6.200	59	58	39	39	02	03	16	40	32	50
20	K60567	6.600	6.500	66	65	30	30	02	03	06	12	14	20

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

S. N O	OP. NO	TC (million cu.mm)		DC						ESR			
				N		L		Mxd		½ HR		1 HR	
		BT	AT	B T	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	I 42030	7.000	7.400	77	53	21	42	05	05	16	10	32	22
22	K98073	7.300	7.200	69	60	26	32	04	04	12	15	42	30
23	I58783	7.300	7.400	65	60	30	41	05	05	14	16	32	16
24	J44324	6.000	6.000	60	57	36	40	04	05	6	10	12	22
25	J97399	4.900	4.9	38	47	50	44	02	04	10	8	20	16
26	L03219	5.400	4.700	61	62	36	36	03	02	16	14	32	40
27	J47444	8.700	8.400	60	73	31	36	23	02	14	14	24	30
28	K60568	6.500	6.500	61	62	35	34	04	04	8	14	20	24
29	K5308	9.200	9.600	70	70	27	41	03	02	4	8	10	12
30	G58335	6.800	6.200	65	58	31	39	04	03	14	12	34	40
31	1779-18	5.2	5.3	66	60	26	34	03	03	4	6	20	12
32	1774-18	4.600	4.600	61	55	32	33	02	02	10	24	26	50
33	K19651	5.000	4.700	55	52	40	42	02	01	20	20	40	42
34	H83252	5.000	5.100	73	60	23	33	01	01	14	18	28	26
35	K47168	4.300	4.500	56	56	40	40	04	04	22	20	46	44
36	G90503	5.000	4.700	52	55	42	38	02	03	20	10	46	22
37	H25390	4.500	4.400	57	45	39	51	01	01	14	6	30	12
38	F75898	5.4	5.0	62	62	30	30	8	8	10	2	22	4
39	H09508	4.600	4.800	70	73	24	25	06	02	10	14	20	28
40	L06690	6.600	4.600	65	65	30	32	05	03	8	16	18	14

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

Sl. No	IP NO	Serum bilirubin (mg/dl)						GLUCOSE PROFILE			
		Direct		Indirect		Total		FAST		P.P.	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	K 95654	0.3	0.36	0.6	0.6	0.9	1.0	90	95	108	175
2	F 006953	0.3	0.23	0.4	0.3	0.4	0.3	83	95	90	86
3	L 10676	0.4	0.6	0.5	0.8	0.9	1.4	90	83	108	76
4	L 10014	0.2	0.3	0.3	0.3	0.5	0.6	127	110	160	148
5	K 61602	0.2	0.4	0.3	0.2	0.5	0.6	89	95	103	110
6	H 33143	0.1	0.3	0.2	0.5	0.3	0.8	117	114	110	127
7	I 68290	0.2	0.4	0.4	0.4	0.6	0.8	360	299	455	435
8	I 20367	0.4	0.4	0.8	0.6	1.2	1.0	117	112	124	117
9	J 13408	0.2	0.2	0.3	0.2	0.5	0.4	217	214	412	397
10	L16992	0.1	0.1	0.3	0.7	0.4	0.8	92	104	145	162
11	K 82380	0.5	0.4	1.0	0.6	1.5	1.0	127	126	143	136
12	K 97879	0.4	0.3	0.7	0.6	1.1	0.9	113	104	166	158
13	J 33561	0.1	0.1	0.3	0.3	0.4	0.4	118	181	229	287
14	G452488	0.1	0.1	0.1	0.1	0.2	0.2	86	85	105	121
15	L17157	0.2	0.9	0.6	0.6	0.8	0.8	107	110	109	105
16	J43232	0.2	0.2	0.4	0.3	0.6	0.5	130	100	188	104
17	J84340	0.1	0.2	0.1	0.2	0.2	0.4	104	110	108	122
18	L00048	0.3	0.4	0.7	0.8	1.0	1.2	101	104	112	116
19	L19986	0.3	0.3	0.6	0.8	1.2	1.2	105	106	113	115
20	K60567	0.6	0.5	0.6	0.5	1.2	1.0	91	94	106	97

Sl. No	IP NO	Serum bilirubin (mg/dl)						GLUCOSE PROFILE			
		Direct		Indirect		Total		FAST		P.P.	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	I 42030	0.1	0.3	0.7	0.7	1.0	1.0	128	120	212	200
22	K98073	0.5	0.4	0.3	0.2	0.5	0.6	97	100	152	140
23	I58783	0.4	0.2	0.2	0.3	0.7	0.5	76	88	172	168
24	J44324	0.1	0.3	0.2	0.4	0.4	0.7	97	110	106	120
25	J97399	0.1	0.4	0.4	1.0	0.2	1.4	93	99	147	159
26	L03219	0.2	0.6	0.3	0.3	0.5	0.8	106	110	112	116
27	J47444	0.2	0.2	0.3	0.5	0.5	0.7	106	110	202	190
28	K60568	0.1	0.1	0.3	0.3	0.4	0.4	137	128	244	228
29	K5308	0.3	0.1	0.2	0.2	0.3	0.3	114	102	139	111
30	G58335	0.3	0.3	1.0	0.7	1.4	1.0	94	108	110	123
31	1779-18	0.6	0.2	0.4	0.4	0.6	0.6	100	97	157	146
32	1774-18	0.3	0.3	0.5	0.6	0.8	0.9	102	86	132	102
33	K19651	0.3	0.5	0.4	0.4	0.9	0.9	115	110	160	138
34	H83252	0.4	0.3	0.2	0.3	0.5	0.6	115	126	189	190
35	K47168	0.2	0.8	0.7	0.4	1.1	1.2	114	110	109	100
36	G90503	0.2	0.1	0.2	0.3	0.4	0.4	110	109	120	157
37	H25390	0.1	0.3	0.5	0.8	0.7	1.1	114	160	105	195
38	F75898	0.2	0.3	0.3	0.3	0.5	0.6	141	88	217	124
39	H09508	0.4	0.4	0.3	0.3	0.5	0.5	258	238	383	378
40	L06690	0.2	0.3	0.5	0.2	0.8	0.5	89	111	110	182

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

S. N	OP.NO	TC Cells/µL		DC						ESR			
				P		L		Mxd		½ HR		1 HR	
		BT	AT	BT	A T	B T	AT	B T	A T	BT	AT	BT	AT
1	K 95654	7.600	9000	65	69	30	27	05	02	16	32	24	50
2	F 006953	6.000	7000	57	67	39	30	04	03	34	40	24	50
3	L 10676	6.200	5,900	75	75	20	21	05	04	16	32	02	04
4	L 10014	7.600	8200	65	67	33	29	02	02	10	8	22	18
5	K 61602	7.500	7100	79	62	18	35	03	03	10	08	20	16
6	H 33143	6.800	6200	60	65	30	30	10	05	8	12	16	24
7	I 68290	6.100	6300	55	65	42	42	03	02	06	12	18	18
8	I 20367	3.600	3.700	60	65	32	29	08	06	20	30	40	35
9	J 13408	6.900	7.200	55	58	41	38	04	02	30	06	60	12
10	L16992	7.400	7.400	55	53	43	41	03	06	8	20	18	30
11	K 82380	8.200	7.000	65	69	31	27	04	04	4	08	10	18
12	K 97879	6.500	4.700	75	60	22	37	03	03	04	04	08	08
13	J 33561	4.900	5.000	65	65	31	32	04	03	06	08	14	20
14	G45248	4.800	4.900	62	63	34	33	04	03	34	35	50	52
15	L17157	9.000	9.100	75	75	20	21	02	04	14	18	20	30
16	J43232	8.600	9.700	69	73	28	24	03	03	16	24	34	50
17	J84340	6.600	6.600	65	64	30	32	05	03	8	10	0	20
18	L00048	9.500	8.500	68	69	26	27	05	05	20	60	40	30
19	L19986	6.400	6.200	59	58	39	39	02	03	16	40	32	50
20	K60567	6.600	6.500	66	65	30	30	02	03	06	12	14	20

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

S. N O	OP. NO	TC (million/ cu.mm)		DC						ESR			
				N		L		Mxd		½ HR		1 HR	
		BT	AT	BT	AT	BT	AT	BT	AT	B	AT	BT	AT
21	I 42030	7.000	7.400	77	53	21	42	05	05	16	10	32	22
22	K98073	7.300	7.200	69	60	26	32	04	04	12	15	42	30
23	I58783	7.300	7.400	65	60	30	41	05	05	14	16	32	16
24	J44324	6.000	6.000	60	57	36	40	04	05	6	10	12	22
25	J97399	4.900	4.9	38	47	50	44	02	04	10	8	20	16
26	L03219	5.400	4.700	61	62	36	36	03	02	16	14	32	40
27	J47444	8.700	8.400	60	73	31	36	23	02	14	14	24	30
28	K60568	6.500	6.500	61	62	35	34	04	04	8	14	20	24
29	K5308	9.200	9.600	70	70	27	41	03	02	4	8	10	12
30	G58335	6.800	6.200	65	58	31	39	04	03	14	12	34	40
31	1779-18	5.2	5.3	66	60	26	34	03	03	4	6	20	12
32	1774-18	4.600	4.600	61	55	32	33	02	02	10	24	26	50
33	K19651	5.000	4.700	55	52	40	42	02	01	20	20	40	42
34	H83252	5.000	5.100	73	60	23	33	01	01	14	18	28	26
35	K47168	4.300	4.500	56	56	40	40	04	04	22	20	46	44
36	G90503	5.000	4.700	52	55	42	38	02	03	20	10	46	22
37	H25390	4.500	4.400	57	45	39	51	01	01	14	6	30	12
38	F75898	5.4	5.0	62	62	30	30	8	8	10	2	22	4
39	H09508	4.600	4.800	70	73	24	25	06	02	10	14	20	28
40	L06690	6.600	4.600	65	65	30	32	05	03	8	16	18	14

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

Sl. No	OP NO	SGOT (IU/dl)		SGPT (IU/dl)		Al.pho (U/dl)		Albumin (g/dl)		Globulin (g/dl)		T.Protein (g/dl)	
		BT	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**
1	K 95654	21	22	28	40.9	100	107	3.9	3.96	3.0	3.9	7.5	7.87
2	F 006953	12	12.1	12	10.5	66	56	3.7	3.6	3.5	3.4	7.3	6.97
3	L 10676	26	18.6	27	22	73	73	3.8	3.5	3.4	3.3	7.2	6.87
4	L 10014	17	17	09	20	56	58	4.1	3.6	2.9	2.7	7.0	7.2
5	K 61602	34	25.1	47	19.3	61	55	3.9	3.9	3.0	3.2	7.0	7.2
6	H 33143	19	17.3	12	16.7	71	67	3.8	3.8	3.4	3.8	7.2	7.9
7	I 68290	18	23	14	25	77	78	4.2	3.3	3	3.1	7.2	7.4
8	I 20367	22	24	19	20	65	56	3.5	3.5	4.2	4.9	8.3	8.00
9	J 13408	22	16	24	18	87	84	4.0	3.8	2.7	2.9	6.7	6.7
10	L16992	16	16	09	11	72	72	3.8	3.7	3.5	3.6	7.3	7.2
11	K 82380	14	15	18	14	86	84	4.3	4.0	3.3	3.3	7.6	7.3
12	K 97879	16	17	08	15	79	79	4.2	4.1	2.3	2.9	6.5	6.9
13	J 33561	20	22	16	19	100	104	3.8	3.2	3.3	3.1	7.1	7.2
14	G45248	16	18	15	15	108	107	3.2	3.1	2.2	2.1	7.4	7.1
15	L17157	18	20	16	18	96	95	3.7	3.9	3.5	3.6	7.2	7.00
16	J43232	18	20	20	20	66	62	3.6	3.6	3.3	3.1	6.8	6.7
17	J84340	19	19.5	20.2	20	99	98	3.6	3.3	3.1	3.8	6.7	6.9
18	L00048	16	16	19	14	107	118	3.7	3.5	3.8	3.9	7.5	7.5
19	L19986	21	20	23	22	148	100	3.6	3.2	3.3	3.1	6.9	7.2
20	K60567	19	15	23	26	76	67	3.2	3.1	2.2	2.5	7.1	7.2

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

Sl. No	OP NO	SGOT (IU/dl)		SGPT (IU/dl)		Al.pho (U/dl)		Albumin (g/dl)		Globulin (g/dl)		T. Protein (g/dl)	
		BT	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**
21	I 42030	10	19	19	18	71	80	3.8	5.0	3.2	3.0	7.7	8.0
22	K98073	18	22	24	25	57	67	3.7	3.9	3.1	3.2	6.8	7.0
23	I58783	15	15	16	10	66	70	3.8	3.7	2.8	3.0	6.6	6.7
24	J44324	18	20	24	23	65	66	3.9	3.7	2.3	2.2	6.7	6.9
25	J97399	21	19	21	17	79	85	4.2	3.8	3.1	3.1	7.2	6.9
26	L03219	12	19	13	19	97	91	4.0	3.8	2.7	2.9	6.7	6.8
27	J47444	19	18	23	17	73	62	3.4	3.7	3.3	3.5	7.0	7.2
28	K60568	16	19	09	19	64	77	04	4.2	3	2.8	7	7.1
29	K5308	22	21	20	24	88	72	4.5	4.3	3.3	3.3	7.8	7.6
30	G58335	32	25	18	20	97	93	4.4	4.4	3.1	3.0	7.5	7.4
31	1779-18	10	12	10	20	104	110	4.2	4.1	3.1	3.2	7.3	7.2
32	1774-18	23	24	28	22	86	99	4.6	4.4	3.0	2.7	7.6	7.1
33	K19651	21	19	21	17	79	85	4.2	3.8	3.1	3.1	7.2	6.9
34	H83252	12	19	13	19	97	91	4.0	3.8	2.7	2.9	6.7	6.8
35	K47168	19	18	23	17	73	62	3.4	3.7	3.3	3.5	7.0	7.2
36	G90503	16	19	09	19	64	77	04	4.2	3	2.8	7	7.1
37	H25390	22	21	20	24	88	72	4.5	4.3	3.3	3.3	7.8	7.6
38	F75898	32	25	18	20	97	93	4.4	4.4	3.1	3.0	7.5	7.4
39	H09508	10	12	10	20	104	110	4.2	4.1	3.1	3.2	7.3	7.2
40	L06690	23	24	28	22	86	99	4.6	4.4	3.0	2.7	7.6	7.1

INVESTIGATIONS OF BEFORE AND AFTER TREATMENT

Sl. No	OP NO	Calcium (mg/dl)		Uric acid mg/dl		TGL mg/dl		Urea (g/dl)		Creatinine (g/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	K 95654	8.9	8.8	5.8	5.1	280	270	13	14.1	0.9	0.8
2	F 006953	8.9	9.8	4.2	3.6	98	67	22	26	0.8	0.8
3	L 10676	9.1	8	7.5	6.0	57	68.5	20	14	1.0	0.98
4	L 10014	8.4	8.9	5.4	5.3	214	250	18	12	0.9	0.8
5	K 61602	8.3	9.6	5.2	5.2	63	92	16	8.9	0.9	0.82
6	H 33143	9.3	7.9	3.2	2.5	88	65	23	30	0.9	0.86
7	I 68290	9.6	9.9	2.6	2.2	61	78	15	18	0.8	0.7
8	I 20367	7.1	7.3	2.1	2.2	158	159	18	14	0.8	0.9
9	J 13408	8.3	9.3	5.4	4.9	107	95	17	21	0.7	0.7
10	L16992	8.8	8.7	4.2	4.7	115	139	21	19	0.8	0.7
11	K 82380	9.8	9.2	5.9	5.8	212	259	13	18	1.0	1.0
12	K 97879	10.2	8.1	6.1	5.4	107	165	20	17	1.1	1.1
13	J 33561	7.9	8.7	3.0	4.1	112	119	17	20	0.8	0.9
14	G45248	8.4	8.2	4.1	3.4	64	75	19	16	0.7	0.9
15	L17157	9.1	9.8	3.8	3.2	125	130	15	20	0.8	0.7
16	J43232	8.9	9.3	5.1	4.9	149	196	18	16	0.9	1.0
17	J84340	8.7	8.9	5.1	5.4	91	109	29	28	0.9	1.0
18	L00048	8.9	9.7	6.9	4.7	134	107	29	23	1.0	1.0
19	L19986	9.5	9.8	3.2	3.0	215	230	19	18	0.8	1.0
20	K60567	8.1	8.0	2.3	2.5	134	138	20	19	0.9	1.1

Sl. No	OP NO	Calcium (mg/dl)		Uric acid mg/dl		TGL mg/dl		Urea (g/dl)		Creatinine (g/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	I 42030	9.7	9.9	5.2	5.3	118	180	21	25	0.8	0.9
22	K98073	8.8	9.1	5.1	5.2	90	99	23	25	0.8	1.0
23	I58783	9.9	8.5	3.5	3.9	103	140	21	24	0.8	0.9
24	J44324	9.2	9.7	4.6	4.2	80	87	24	21	0.8	1.1
25	J97399	8.1	9.6	3.1	4.6	180	165	15	14	0.9	0.9
26	L03219	8.9	9.7	6.9	4.7	134	107	29	23	1.0	1.0
27	J47444	8.9	7.6	5.8	5.9	156	159	14	13	1.1	1.0
28	K60568	8.3	9.6	5.2	5.2	63	92	16	8.9	0.9	0.82
29	K5308	9.3	7.9	3.2	2.5	88	65	23	30	0.9	0.86
30	G58335	9.6	9.9	2.6	2.2	61	78	15	18	0.8	0.7
31	1779-18	7.1	7.3	2.1	2.2	158	159	18	14	0.8	0.9
32	1774-18	8.3	9.3	5.4	4.9	107	95	17	21	0.7	0.7
33	K19651	8.8	8.7	4.2	4.7	115	139	21	19	0.8	0.7
34	H83252	9.8	9.2	5.9	5.8	212	259	13	18	1.0	1.0
35	K47168	10.2	8.1	6.1	5.4	107	165	20	17	1.1	1.1
36	G90503	7.9	8.7	3.0	4.1	112	119	17	20	0.8	0.9
37	H25390	8.4	8.2	4.1	3.4	64	75	19	16	0.7	0.9
38	F75898	9.1	9.8	3.8	3.2	125	130	15	20	0.8	0.7
39	H09508	8.9	9.3	5.1	4.9	149	196	18	16	0.9	1.0
40	L06690	8.7	8.9	5.1	5.4	91	109	29	28	0.9	1.0

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. NO	OP NO	URINE									
		Before Treatment					After Treatment				
		Albumin	Sugar		Deposits		Albumin	Sugar		Deposits	
			F	PP	Pus Cells	Epi Cels		F	PP	Pus Cells	Epi. Cells
1	K 95654	NIL	NIL	NIL	1-3	1-2	NIL	NIL	NIL	1-2	1-2
2	F 006953	NIL	NIL	NIL	4-2	2-4	NIL	NIL	NIL	4-2	2-4
3	L 10676	NIL	NIL	NIL	1-3	2-4	NIL	NIL	NIL	1-3	2-4
4	L 10014	NIL	NIL	NIL	6-8	5-7	NIL	NIL	NIL	7-8	6-7
5	K 61602	NIL	NIL	NIL	1-3	2-4	NIL	NIL	NIL	1-3	2-4
6	H 33143	NIL	NIL	NIL	1-3	1-2	NIL	NIL	NIL	1-3	1-2
7	I 68290	NIL	++	+++	5-6	2-4	NIL	++	+++	5-6	2-4
8	I 20367	NIL	NIL	NIL	2-4	2-4	NIL	NIL	NIL	1-2	2-3
9	J 13408	NIL	+	++	1-2	2-4	NIL	++	+++	2-4	6-8
10	L16992	NIL	NIL	NIL	2-4	3-5	NIL	NIL	NIL	2-3	3-4
11	K 82380	NIL	NIL	NIL	6-8	2-4	NIL	NIL	NIL	6-8	7-8
12	K 97879	NIL	NIL	NIL	2-3	2-3	NIL	NIL	NIL	2-3	2-3
13	J 33561	NIL	NIL	+	2-3	1-2	NIL	NIL	+	2-4	1-2
14	G45248	NIL	NIL	NIL	2-3	2-3	NIL	NIL	NIL	6-8	4-6
15	L17157	NIL	NIL	NIL	4-5	2-3	NIL	NIL	NIL	4-5	2-3
16	J43232	NIL	NIL	NIL	2-4	3-5	NIL	NIL	NIL	2-3	2-4
17	J84340	NIL	NIL	NIL	2-3	2-4	NIL	NIL	NIL	2-3	3-5
18	L00048	NIL	NIL	NIL	6-7	6-4	NIL	NIL	NIL	6-7	6-4
19	L19986	NIL	NIL	NIL	6-7	2-4	NIL	NIL	NIL	5-6	3-5
20	K60567	NIL	NIL	NIL	1-2	1-2	NIL	NI	NIL	4-5	4-6

S. NO	OP NO	URINE									
		Before Treatment					**After Treatment**				
		Albu min	**Sugar**		**Deposits**		**Albu min**	**Sugar**		**Deposits**	
			F	PP	**Pus Cells**	**Epi. cells**		F	PP	**Pus Cells**	**Epi. Cells**
21	I 42030	NIL	NIL	NIL	1-2	2-4	NIL	NIL	NIL	1-2	2-4
22	K98073	NIL	NIL	NIL	1-2	2-3	NIL	NIL	NIL	1-2	2-3
23	I58783	NIL	NIL	NIL	2-3	2-3	NIL	NIL	NIL	1-3	3-5
24	J44324	NIL	NIL	NIL	4-5	2-3	NIL	NIL	NIL	4-5	2-3
25	J97399	NIL	NIL	NIL	3-5	3-5	NIL	NIL	NIL	1-3	1-3
26	L03219	NIL	NIL	NIL	1-3	1-3	NIL	NIL	NIL	1-3	1-3
27	J47444	NIL	NIL	NIL	1-2	6-8	NIL	NIL	NIL	10-12	6-8
28	K60568	NIL	NIL	NIL	1-2	2-4	NIL	NIL	NIL	1-2	1-4
29	K5308	NIL	NIL	NIL	2-4	1-2	NIL	NIL	NIL	4-6	3-5
30	G58335	NIL	NIL	NIL	2-3	2-3	NIL	NIL	NIL	2-4	2-4
31	1779-18	NIL	NIL	NIL	2-4	2-4	NIL	NIL	NIL	2-4	2-4
32	1774-18	NIL	NIL	NIL	3-5	1-3	NIL	NIL	NIL	2-4	2-4
33	K19651	NIL	NIL	NIL	2-3	1-2	NIL	NIL	NIL	2-3	1-2
34	H83252	NIL	NIL	NIL	4-6	2-4	NIL	NIL	NIL	4-6	2-4
35	K47168	NIL	NIL	NIL	2-4	1-3	NIL	NIL	NIL	2-4	1-3
36	G90503	NIL	NIL	NIL	4-6	3-5	NIL	NIL	NIL	4-6	3-5
37	H25390	NIL	NIL	NIL	1-3	3-5	NIL	NIL	NIL	2-4	2-4
38	F75898	NIL	NIL	NIL	2-3	2-3	NIL	NIL	NIL	2-4	2-4
39	H09508	NIL	NIL	NIL	1-2	1-3	NIL	NIL	NIL	1-2	1-3
40	L06690	NIL	NIL	NIL	2-3	2-3	NIL	NIL	NIL	1-3	2-4

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 ± 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.

PAIN ASSESSMENT SCALE BEFORE AND AFTER TREATMENT:

Pain scale	Sample size	Mean	Standard deviation	95% confidence interval	Significant
Before treatment	**40**	**7.125**	**0.9388**	**6.82-7.42**	**p<0.0001.**
After treatment	**40**	**1.9**	**1.317**	**1.49 - 2.31**	

PAIN ASSESSMENT AT START OF TREATMENT BETWEEN TWO GROUPS:

	Sample size	Mean	Standard deviation	't' value	'p' value
Without Varmam	**20**	**7**	**1.076**	**0.0017**	**0.99**
With Varmam	**20**	**7.25**	**0.7864**		

PAIN ASSESSMENT AT END OF TREATMENT BETWEEN TWO GROUPS

	Sample size	Mean	Standard deviation	't' value	'p' value
Without Varmam	**20**	**1.85**	**1.348**	**0.0027**	**0.0998**
With Varmam	**20**	**1.95**	**1.317**		

There is no significant difference between with and without varmam treatment groups before the start of treatment.

DISCUSSION

The purpose of this trail is evaluate to the therapeutic efficacy of the drug ***"Kandathri Chooranam"*** (Internal), ***"Erandai Thylam"*** (External) to reduce pain, swelling, restriction of movements and other clinical symptoms of ***Azhal Keel Vayu***.

The clinical features of *Azhal Keel Vayu* can be correlated with Osteoarthritis in modern science. OA is a degenerative joint disease involving the cartilage and many of its surrounding tissues. In addition to damage and loss of articular cartilage, there is remodelling of subarticular bone, osteophyte formation, ligamentous laxity, weakening of periarticular muscles and in some cases, synovial inflammation.

The drugs which possess Anti-Vatha property as mentioned in Siddha literature were selected and the trial drugs were prepared in *Gunapadam* practical laboratory of National Institute of Siddha, after getting proper authentication of raw drugs from the Medicinal botany department at NIS, Chennai 47, under the supervision of the members of the teaching faculty and guided by the Head of the Department of *Sirappu Maruthuvam* of the National Institute of Siddha, Chennai - 47. The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

The Biochemical qualitative analysis was done at the Biochemistry lab of NIS. The Bio-chemical analysis of ***"Kandathri chooranam"*** had shown the presence of Chloride, Carbonate, Calcium, Magnesium, Ammonium, Mercury, Arsenic, Starch, Reducing Sugar Lead, Aluminium, ,Iron, Zinc Tannic acid, starch, unsaturated compound and Alkaloids.

The clinical study was conducted with a well defined protocol and a proper proforma after the approval of the Institutional Ethical Committee. After screening patients reporting at the OPD of department of Sirappu Maruthuvam, 40 cases were selected for induction to the trial. Before enrollment into the trial the informed consent was obtained from the patients.

40 patients of both genders were recruited for this study. Among the 40 patients were treated in the OPD/IPD . Out of 40patients, were 20 patients had treated under the *varmam* therapy along with the trial drugs. Rest of them 20 patients were treated trial drug alone.

The treatment was aimed at normalizing the derangement of *thodams* and providing relief from symptoms. By giving purgation we can normalize the deranged *Vatham*.

"விரேசனத்தால் வாதந் தாழும்"

Before treatment the patients were advised to take *Meganatha kuligai* pills- 2nos with hot water in early morning for purgation.

The patients were treated with trial drugs ***"Kandathri Chooranam"*** (internal) twice a day with hot water and ***"Erandai Ennai"*** (external) for 45 days. Patients were instructed to take the medicines regularly advised to follow *pathiyam* (avoid tamarind, tubers, etc) and advised to avoid cold exposure. 40 Patients were asked to visit the hospital once in 7 days and drugs were given for 45days and the clinical assessment was done on 1^{st} day, 12^{th} day, 24^{th} day, 36^{th} day and 45^{th} day.

For Patients the drugs were given 1-45 days and the clinical assessment was done daily.

After the treatment, for further follow up, patients were advised to visit the Out-Patient ward of Department of Sirappu Maruthuvam .

CLINICAL MANIFESTATIONS:

Pain in the knee joint was present in 40 cases. Swelling was Present in 13 cases. The other important features were morning stiffness in 3 cases, tenderness in 10 cases, restricted movements in 10 cases, crepitation were observed in 17 cases.

LABORATORY INVESTIGATIONS:

- Laboratory investigations were done for all the cases before and after treatment. There were no variations in hepatic, renal and other parameters.
- The radiographic studies showed narrowed joint space and presence of Osteophytes. The trial drug showed improvement in prognosis of the disease clinically rather than in radiographic changes.

EFFECT OF TREATMENT:

Good improvement was observed in 25 (62.5%) Patients, moderate improvement in 4 (10%) and mild improvement in 8(20%). The mean pain score beforet and after treatment is Very Significant.

Treatment status	Mean± Std deviation	**t-value**	**p-value**
Before treatment	7 ± 1.076	0.0017	0.99
After treatment	1.85±1.348	0.0027	0.0098

EFFECT OF *VARMAM*:

20 patients are treated with *Varmam* along with the trial drug. The results are compared at the end of the study. There is no significant difference between with and without varmam treatment groups before the start of treatment. The mean pain score before and after treatment it was observed in Extremly Significant. Hence this study reveals the importance of *Varmam* therapy in the treatment of Osteoarthritis.

Treatment status	**Mean± Std deviation**	**t-value**	**p-value**
Before treatment	7.25±0.7864	0.0017	0.99
After treatment	1.95±1.317	0.0027	0.0098

SUMMARY

The clinical study on *Azhal Keel Vayu* with reference to its aetiology, pathogenesis, investigations, clinical features, diagnosis and treatment were conducted at the Sirappu Maruthuvam Department, Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai – 47.

The drugs administered in the clinical study were used only after getting authentication from concern department and careful purification process.

40 cases of both the sexes with the signs and symptoms of *Azhal Keel Vayu* were selected in the age group within 30 to 65 for the study. Out of 40patients, were 20 patients had treated under the *varmam* therapy along with the trial drugs. Rest of them 20 patients were treated trial drug alone..

All the details about the study and the drugs were informed to the patients in their vernacular language, dietary regimen and information sheet were given to them and signed consent forms were obtained from them. Before starting the treatment, the blood samples of the selected patients were subjected to investigation.

On the first day of the treatment, purgation was given by administering *Meganatha kuligai* pills-2 nos with hot water in the early morning to normalize the deranged *kuttram.*

From the second day onwards, the patients were treated with the trial drug *"Kandathri Chooranam"* 2gm bid with Cold water was given internally and *"Erandai Thylam"* externally. Every 8thday, the patients were assessed for clinical improvement and adverse effects.

Before treatment (0th day) and at the end of the treatment (45th day) the laboratory investigations were done. The x-ray of the affected Joints were taken. The improvement was assessed.

During the course of treatment there were no adverse effects or unwanted drug reactions in Gastro intestinal tract, Respiratory system, Cardio vascular system and excretory systems.

20 patients are treated with *varmam* along with the trial medicine. The results are compared at the end of the study. The mean pain score of the 20 patients who received *varmam* was reduced Hence *varmam* treatment along with trial medicine is effective in the treatment of Osteoarthritis.

The study results showed that 62.5 % had Good improvement, 10 % had Moderate improvement and 20 % had mild improvement. The pain assessment was done in all the 40patients participated in the trial using the universal pain assessment scale and at the end of the study, the results showed, the mean pain score was reduced .

CONCLUSION

The study results showed that the efficacy of trial drug *"Kandathri Chooranam"* which is siddha herbal formulation.It was found to be good resulting on *Azhal Keelvayu* patients in reducing clinical symptoms like pain ,swelling, restricted movements.

Varmam treatment along with the trial drugs showed no significant prognosis when compared to patients treated only with trial drugs. Hence the study reveals the importance of *Varmam* in treating *Azhal Keel Vayu*.

Clinically, no adverse effects were reported during the trial and the laboratory investigations were also within normal limits. So, the drug is assumed to be safe for humans.

Hence the study concludes that, the trial drugs are clinically effective in reduction of pain, swelling, restriction of movements.

Because of the encouraging clinical results, it could be concluded that ***"Kandathri Chooranam"*** (Internally) and **"*Erandai thylam*"** (Externally) are effective in the treatment of *Azhal Keel Vayu* (Osteoarthritis).

However further work with large number of patients should be carried out towards finding the ideal dose response.

BIO-CHEMICAL ANALYSIS: Qualitative Analysis

SL. NO	EXPERIMENT	OBSERVATION	INFERENCE
1.	Appearance of the sample	Blackish Brown in Colour	
2.	**Solubility:** a. A little of the sample is shaken well with distilled water. b. A little of the sample is Shaken well with con. Hcl Con. H_2SO_4.	Sparingly soluble Sparingly soluble	**Presence of Silicate**

Preparation of the Extract

2 gm of ***kandathri chooranam*** was weighed accurately and placed in a 250 ml clean beaker. Then 50 ml distilled water was added and dissolved well. Then it is boiled well for about 10 minutes. It was cooled and filtered in a 100 ml volumetric flask and then it was made up to 100 ml with distilled water. This fluid was taken for analysis.

SL. NO.1	EXPERIMENT	OBSERVATION	INFERENCE
TEST FOR ACID RADICALS			
1.	**Test For Sulphate:** a. 2 ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution.	Cloudy appearance not present	Absence of Sulphate.
2.	**Test For Chloride:** 2 ml of the above prepared Extract is added with dil. HNO_3 till the effervescence ceases. Then 2 ml of silver nitrate solution is added.	Cloudy appearance present	**Presence of Chloride**.
3.	**Test For Phosphate:** 2 ml of the extract is treated with 2ml of ammonium molyb date solution and 2 ml of con. HNO_3	No Cloudy yellow appearance	Absence of Phosphae.
4.	**Test For Carbonate:** 2m1 of the extract is treated with 2m1 magnesium sulphate Solution	Cloudy appearance present	**Presence of Carbonate**

5.	**Test for fluoride & oxalate** 2 m1 of The Extract Is Added With 2m1of Acetic Acid and 2 m1 calcium Chloride solution and heated.	No Cloudy appearance.	Absence of Fluoride & Oxalate
6.	**Test for Nitrite:** 3drops of extract is placed on a filter paper,on that 2 drops of acetic Acid and 2 drops of benzidine solution is placed.	No characteristic Changes.	Absence of nitrite.
7.	**Test For Borate:** 2 pinches of the substance is made into paste by using sulphuric acid and alcohol (95%) and introduced into the blue flame.	Bluish green colour flame not appeared.	Absence of borate.

	II. TEST FOR BASIC RADICALS		
	Test For Lead: 2 m1of the extract is added with 2m1of potassium iodide solution	Yellow precipitate is obtained	**Presence of Lead.**
2.	**Test for Copper:** a. One pinch of substance is made into paste with con. Hcl in a watch glass and introduced into the non-luminous part of the flame. b. 2 ml of extract is added with excess of ammonia solution.	No Bluecolour flame precipitate No Bluecolour precipitate	Absence of Copper. Absence of Copper.
3.	**Test For Aluminium:** Take the 2m1of the extract sodium hydroxide is added in drops to excess.	characteristic changes	**Presence of Aluminium**

4.	**Test For Iron: (Ferrous)** To the 2 ml of extract 2m1 ammonium thiocyanate solution and 2m1of con.HNO_3 is added.	Blood red colour Appearance	**Presence of Iron.**
5.	**Test For Zinc:** To 2m1 of the extract sodium hydroxide solution is added in drops to excess.	White precipitate is Formed	**Presence of Zinc**.
6.	**Test For Calcium:** 2m1 of the extract is added with 2m1 of 4% ammonium oxalate Solution.	Cloudy appearance and white precipitate is obtained	**Presence of Calcium**.
7.	**Test For Magnesium:** To 2ml of extract sodium hydroxide solution is added in drops to excess.	White precipitate is obtained.	**Presence of Magnesium**
8.	**Test For Ammonium:** To 2ml of extract few ml of Nessler's reagent and excess of sodium hydroxide solution are added.	Brown colour is appeared**.**	**Presence of Ammonium**
9.	**Test For Potassium:** A pinch of substance is treated with 2ml of sodium nitrite solution and then treated with 2m1 of cobalt nitrate in 30% glacial acetic acid.	No Yellowish precipitate is obtained	Absence of Potassium.
10.	**Test For Sodium:** 2 pinches of the substance is made into paste by using HCL and introduced into the blue flame of Bunsen burner.	No Yellow colour Flame appeared.	Absence of Sodium.
11.	**Test For Mercury:** 2m1 of the extract is treated with 2ml of sodium hydroxide solution.	Yellow precipitate is obtained	**Presence of Mercury.**
12.	**Test For Arsenic:** 2m1 of the extract is treated with 2m1 of sodium hydroxide solution.	Brownish red Precipitate is obtained	**Presence of Arsenic.**

III. MISCELLANEOUS			
1.	**Test for Starch:** 2ml of extract is treated with weak iodine solution.	Blue colour developed	**Presence of Strarch.**
2.	**Test For Reducing Sugar:** 5. ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.	Brick red colour developed	**Presence of Reducing sugar.**
3.	**Test For The Alkaloids:** a. 2m1 of the extract is treated with 2ml of potassium Iodide solution. b. 2m1 of extract is treated with 2ml of picric acid. c. 2m1 of the extract is treated with 2ml of phosphotungstic acid.	Red colour developed Yellow colour developed White precipitate developed	**Presence of Alkaloid.** **Presence of Alkaloid.** **Presence of Alkaloid.**
4.	**Test for Tannic Acid:** 2ml of extract is treated with 2ml of ferric chloride solution.	Black precipitate is obtained	**Presence of Tannic acid.**
5.	**Test for Unsaturated Compound:** To the 2ml of extract 2ml of Potassium Permanganate solution is added.	Potassium Permanganate is decolourised	**Presence of Unsaturated Compound.**
6.	**Test For Amino Acid:** 2 drops of the extract is placed on a filter paper and dried well and 2 ml of biuret reagent is added	No Violet colour developed	Absence of Amino acids.

7.	**Test For type of Compound:** 2ml of the extract is treated with 2 ml of ferric chloride solution.	Green colour developed	**Presence of oxy quinole epinephrine and pyro catechol.**
		No Red colour developed	Anti pyrine, Aliphatic amino acids and Meconic acid are absent.
		No Violet colour developed	Apomorphine, Salicylate and Resorcinol are absent.
		No blue colour developed	Morphine, Phenol cresol and hydro quinone are absent

RESULT:

The Bio-chemical analysis of *Kandathri chooranam* had shown the presence of Chloride,Carbonate, Lead, Aluminium, Iron, Zinc, Calcium, Magnesium, Ammonium, Mercury,Arsenic, Starch, Reducing Sugar, Alkaloids Unsaturated Tannic acid, Compounds.

CERTIFICATE

Ministry of AYUSH

NATIONAL INSTITUTE OF SIDDHA

Ministry of AYUSH, Government of India

Tambaram Sanatorium, Chennai - 600 047.

WORKSHOP ON
RESEARCH METHODOLOGY & BIOSTATISTICS

This is to certify that

Dr. V. RUBINI

has participated in the above Workshop held from 16.04.2018 to 20.04.2018 conducted by the Dept. of Noi Naadal, at National Institute of Siddha, Tambaram Sanatorium, Chennai-600 047.

Dr. G.J. Christian
Coordinator
HoD, Dept. of Noi Naadal,
National Institute of Siddha

Prof.Dr.V.Banumathi
Director,
National Institute of Siddha
Chennai - 600 047.

NATIONAL INSTITUTE OF SIDDHA
राष्ट्रीय सिद्ध संस्थान -
Ministry of AYUSH - आयुष मंत्रालय
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ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/Res/IEC/17-18 Date: 28-12-2017

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.V.Rubini, M.D(S) – II year, Department of Sirappu Maruthuvam - Dissertation –	
Protocol title: Comparative clinical trial of Siddha drugs ***Kandaathri Chooranam*** internally and ***Earandai Thylam*** externally in the treatment of ***Azhal Keel vaayu*** (Osteo arthritis) with and without Varmam therapy.	
Documents filed	1) Protocol, 2) Data Collection forms 3) Patient Information Sheet 4) Consent form 5) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	**Yes**
Informed consent documents	**Yes**
Any other documents	**-**
Date of IEC approval & its number	**NIS/13-IEC/2017-1-03/ 22-11-2017**

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, Review periodically, any SAE occurring in the course of the study, any changes in the protocol and submission of final report

Chairman

Member Secretary

NATIONAL INSTITUTE OF SIDDHA CHENNAI 600 047

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Kandathiri chooranam"** (Internal) and **"Eranda Thylam"** (External) taken up for Post Graduation Dissertation studies by **Dr.V.Rubini** M.D.(S). II year. Department of Sirappu Maruthuvam. 2018. are identified through Visual inspection. Experience. Education & Training. Organoleptic characters. Morphology and Taxonomical methods as

Zingiber officinale Rosc. (Zingiberaceae). Fresh Rhizome
Cuminum cyminum Linn. (Apiaceae). Fruit
Piper nigrum Linn. (Piperaceae). Fruit
Taxus baccata Linn. (Taxaceae). Leaf
Costus speciosus (Koen.) Sm. (Costaceae). Root
Syzygium aromaticum (Linn.) Merr. & L.M. Perry (Myrtaceae). Flower bud
Embelia ribes Burm. f. (Myrsinaceae). Fruit
Ricinus communis Linn. (Euphorbiaceae). Seed oil
Curcuma longa Linn. (Zingiberaceae). Finger rhizome
Brassica juncea (Linn.) Czern. & Coss. (Brassicaceae). Seed
Allium sativum Linn. (Liliaceae). Bulb
Acalypha indica Linn. (Euphorbiaceae). Leaf

MEDICINAL BOTANY ★ CHENNAI 600 047 ★ National Institute of Siddha

Certificate No: NISMB3452018

Date: 10-07-2018

Authorized Signatory

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

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

DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"KANDATHIRI CHOORANAM"*** (INTERNAL) AND **"*ERANDAI THAILAM"*** (EXTERNAL) IN THE TREATMENT OF ***"AZHAL KEEL VAYU"*** (OSTEOARTHRITIS OF KNEE JOINT) WITH AND WITHOUT VARMAM THERAPY.

Principal Investigator: Dr.V.Rubini

FORM I - SCREENING & SELECTION PROFORMA

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

INCLUSION CRITERIA

- Whether age is between 30-65 YES\ NO
- Sex M \ F
- Pain & Swelling of both knee joints. YES\ NO
- Crepitations YES\ NO
- Stiffness & Restricted movements YES\ NO
- Willing to attend OPD or admission in IPD for the trial YES\ NO
- Willingness for consent YES\ NO
- Willing to give specimen of blood for the investigation YES\ NO
- Willing to undergo radiological investigation YES\ NO

EXCLUSION CRITERIA

- Cardiac disease YES\ NO
- Rheumatoid arthritis YES\ NO
- Tuberculosis of knee YES\ NO
- Septic arthritis YES\ NO
- Gonococcal arthritis YES\ NO
- Pregnancy and lactation YES\ NO
- Chronic kidney disease YES\ NO
- Patient with any other serious systemic illness YES\ NO
- H/O diabetes mellitus YES\NO

ADMITTED TO TRAIL

YES ☐ NO ☐
If Yes, OPD ☐ IPD ☐
Serial NO: ☐

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 SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"KANDATHIRI CHOORANAM"*** (INTERNAL) AND **"ERANDAI THAILAM"** (EXTERNAL) IN THE TREATMENT OF ***"AZHAL KEEL VAYU"*** (OSTEOARTHRITIS OF KNEE JOINT) WITH AND WITHOUT VARMAM THERAPY.

Principal Investigator: Dr.V.Rubini

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

FORM II-A – HISTORY TAKING PROFORMA

PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES SPECIFY DURATION	AMOUNT/Qty
Smoking				
Tobacco Chewing				
Alcohol				
Narcotic Drug Addiction				

HISTORY OF PREVIOUS ILLNESS AND TREATMENT TAKEN:

FAMILY HISTORY:
Whether this problem runs in family? 1. Yes 2. No
If yes, mention the relationship of affected person(s)
1._____
2._____

DIETARY STYLE: 1. Vegetarian 2. Non-vegetarian

MENSTURAL AND OBSTETRIC HISTORY:

FORM –II B

GENERAL EXAMINATION:

		Yes	No
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.	:		
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) ☐
5. Ilavenil kaalam (Chithirai-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 reg.)	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

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Praanan								
Abaanan								
Samaanan								
Udhaanan								
Viyaanan								
Naagan								
Koorman								
Kirukaran								
Devathathan								
Dhananjeyan								

B) AZHAL

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Analakam								
Ranjakam								
Saathakam								
Prasakam								
Aalosakam								

C) IYYAM

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Avalambagam								
Kilethagam								
Pothagam								
Tharpagam								
Santhigam								

10. ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

NAADI	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day

II. SPARISAM: [PALPATION]

Day	SPARISAM
0th day	
8th day	
15th day	
22nd day	
29th day	
36th day	
43rd day	
49th day	

III. NAA: [TONGUE]

NAA	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day

IV. NIRAM: [COMPLEXION]

1. Vadham ☐
2. Pitham ☐
3. Kabam ☐

V. MOZHI: [VOICE]

1. High Pitched ☐
2. Low Pitched ☐
3. Medium Pitched ☐

VI.VIZHI: [EYES]

VIZHI	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th 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 needathu/ Snake like pattern		
Azhipol paraviyathu Annular/Ringedpattern		
Muththothu ninrathu Pearlbeadepattern		
Other patterns		

CLINICAL EXAMINATION:

LOCOMOTOR SYSTEM:

CLINICAL SYMPTOMS:

Affected knee joints:	Right		Left		Both		
Pain in knee joint:	Mild		Moderate		Severe		
Onset:	Sudden		Gradual				

CLINICAL EXAMINATION OF KNEE JOINT

I.INSPECTION:

	0^{th} day	8^{th} day	15^{th} day	22^{nd}day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
Attitude:								
swelling								
Skin over the knee joints								
Muscle wasting								
Deformity								

II.PALPATION:

	0^{th} day	8^{th} day	15^{th} day	22^{th} day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
Tenderness								
Crepitation								
Local heat								

III. MOVEMENTS

	0^{th} day	8^{th} day	15^{th} day	22^{nd}day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
Flexion								
Extension								

IV. JOINT MESUREMENT:

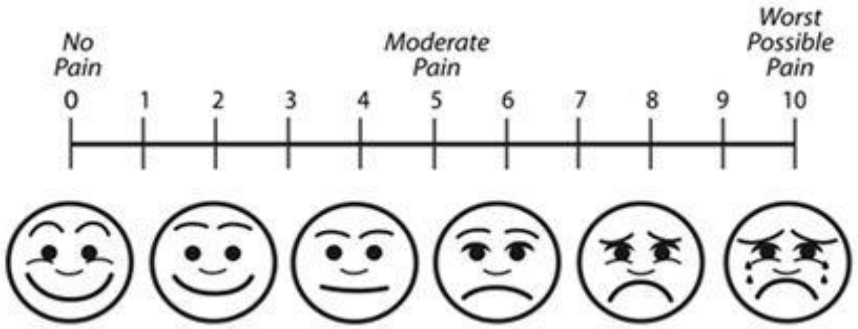
A. HEALTH ASSESSMENT QUESTIONNAIRE:

	0^{th} day	8^{th} day	15^{th} day	22^{nd}day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
PAIN A. Onset: Sudden/Gradual								
B. Early morning Stiffness (Present/absent)								
C. Nature of pain (Mild/ Moderate/ Severe)								
D. Aggravating factor- Movement (Yes/No)								
E. Relieving factor –Rest (Yes/No)								
G. Tenderness (Present/absent)								
RESTRICTION OF MOVEMENT (Fully/Partial/No) Knee joints								

A. UNIVERSAL PAIN ASSESMENT SCALE:

Pain Intensity Scale: 0 to 10

(from Simkin, P. (2010), Pain Medications for Labor & Birth (PowerPoint). Waco, Childbirth Graphics



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

B. RESTRICTED MOVEMENT ASSESSMENT SCALE:

Grade 1 - Fit for all activities, do their work without support.

Grade II - Mild pain present in knee joint, mild restricted movements. Grade III - Pain present in knee joint, moderate restriction of movements. Grade IV - Severe pain, bed ridden.

(Ref: Clinical manual for nursing practice (National Institute of Health Warren Grant Magnuson Clinical Centre

C .Questionnaire of Osteoarthritis :

Name
Age

Which knee is bothering you?

Right Left Both

Did your knee pain start with a specific injury?

Yes No

If yes: Date of injury:

Mechanism of injury :

Did you feel a pop or snap with the injury?

Yes No
Is the injury work related?

Yes No
Did your pain start with a particular sport or activity?

Yes No
If yes, what started the pain?

If there was no injury, when did the pain start?

What part of your knee hurts? Front Inside Outside Back
What are your primary sports and/or activities?

How would you describe your pain? (constant, intermittent, mild, severe, etc.)

Do any of the following increase your pain?

Prolonged walking: Yes Minimally No

Prolonged standing: Yes Minimally No

Going up or down stairs: Yes Minimally No

Prolonged sitting: Yes Minimally No
Getting up from a sitting position: Yes Minimally No

Kneeling or squatting: Yes Minimally No

Pivoting or twisting motions: Yes Minimally No

Running: Yes Minimally No

Sports: Yes Minimally No

Is there anything else that increases your pain?

Do any of the following decrease your pain?

Rest: Yes Minimally No

Ice: Yes Minimally No

Heat: Yes Minimally No

Do you have any of the following symptoms?
Weakness in your leg: Yes Minimally No

Giving way or buckling of your knee: Yes Minimally No

Locking of your knee (unable to fully straighten): Yes Minimally No

Clicking or catching in your knee: Yes Minimally No

Grinding sensation in your knee: Yes Minimally No

Swelling of your knee: Yes Minimally No

Stiffness: Yes Minimally No

Pain at night: Yes Minimally No

Numbness or tingling in your leg: Yes Minimally No

Are there any other symptoms that we need to know about regarding your knee?
Have you had any prior surgery to your knee(s)? Yes No

If yes, what type of surgery did you have and when did you have the surgery?

Have you had any prior treatment for your knee pain such as:

Cortisone injections: Yes No

Synvisc, Euflexxa or "Gel" injections: Yes No

Physical therapy: Yes No

Do you use any ambulatory aids (cane, crutches, walker) Yes No

Have you had any x-rays taken of your knee(s): Yes No

If yes: Date of x-rays:

X-ray facility

Have you had an MRI of your knee(s): Yes No

If yes: Date of MRI:
Is there anything else we need to know about your knee pain?

FORM II-C-VARMAM ASSESSMENT FORM

VARMAM POINTS TO BE APPLIED TO THE PATIENT:

- Kaal Mootu Varmam (Varma Viralalavu Nool)
- Komberi (Varma soothiram 101)
- Viruthi (Varma laada soothiram 300)
- Ullangal Vellai(Adivarma sootcham 500

Day	Date	Varmam	Day	Date	Varmam
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**		
Day 16			**Day 40**		
Day 17			**Day 41**		
Day 18			**Day 42**		
Day 19			**Day43**		
Day 20			**Day 44**		
Day 21			**Day 45**		
Day 22			**Day 46**		
Day 23			**Day 47**		
Day 24			**Day 48**		

Date:
Station:
Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"KANDATHIRI HOORANAM"*** (INTERNAL) AND ***"ERANDAI THAILAM"*** (EXTERNAL) IN THE TREATMENT OF ***"AZHAL KEEL VAYU"*** (OSTEOARTHRITIS OF KNEE JOINT) WITH AND WITHOUT VARMAM THERAPY.

Principal Investigator: Dr.V.Rubini

1. SERIAL NO: **2. OP /IP NO:**
3. NAME: **4. AGE/GENDER:**

FORM -III - LABORATORY INVESTIGATIONS

BLOOD INVESTIGATIONS		**NORMAL VALUES**	**BEFORE TREATMENT**	**AFTER TREATMENT**
Hb(gm/dl)		**M:13-18** **W:11-16**		
T.RBC(millions cells /Cu.mm)		**M:4.5-6.5** **W:3.5-5.5**		
ESR (mm)	**½ hr.**	**-**		
	1 hr.	**M:0-10** **W:0-20**		
T.WBC (Cells /Cu.mm)		**4000-11000**		
Differential Count (%)	**Polymorphs**	**40-75**		
	Lymphocytes	**20-35**		
	Monocytes	**2-10**		
	Eosinophils	**1-6**		
	Basophils	**0-1**		

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Blood glucose (mg/dl)	Fasting	70-110		
	PP	80-140		
Lipid profile (mg/dl)	Serum cholesterol	150-200		
	HDL	30-60		
	LDL	Up to 130		
	VLDL	40		
	TGL	Up to 160		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
LFT (mg/dl)	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-0.2		
	Indirect bilirubin	0.2-0.7		
	Total protein	6-8		
	Serum Albumin	3.5-5.5		
	Serum globulin	2-3.5		
	SGOT (IU/L)	0-40		
	SGPT (IU/L)	0-35		
	Alkaline phosphatase	80-290		
	Serum calcium	9-11		
	Serum phosphorus	2-5		
	Serum Uric acid	M:3-9 W: 2.5-7.5		
CRP				
ASO titre				
RA factor				

B.URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar (Fasting) **(PP)**		
Deposits		
Bile salts		
Bile pigments		

C.RADIOLOGICAL EXAMINATIONS

X- Ray: Knee joint:

1. **Antero posterior**
2. **Lateral view**

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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Principal Investigator: Dr.V.Rubini

FORM - IV (DRUG COMPLIANCE FORM)

SERIAL NO: **OP/IP NO:**

NAME:
AGE/GENDER:
DRUGNAME:SAGALAVATHACHOORANAM

On 1st day-Date: Drugs issued: (Gram) Drugs returned: (Gram)
On 8th day-Date: Drugs issued: (Gram) Drugs returned: (Gram)
On 15th day-Date: Drugs issued: (Gram) Drugs returned: (Gram)
On 22th day-Date: Drugs issued: (Gram) Drugs returned: (Gram)
On 29th day-Date: Drugs issued: (Gram) Drugs returned: (Gram)
On 36th day-Date: Drugs issued: (Gram) Drugs returned: (Gram)
On 43th day-Date: Drugs issued: (Gram) Drugs returned: (Gram)

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

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

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FORM V – PATIENT INFORMATION SHEET

Name of Principal Investigator: Dr.V.Rubini

Name of the institute: National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I Dr.V.Rubini Studying M.D (Siddha) at National Institute of Siddha, Tambaram Sanatorium is doing a trial on *AZHALKEEL VAYU* (OSTEOARTHRITIS). Osteo arthritis is a most common degenarative 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 *KANDATHIRI CHOORANAM* (Internal medicine- 1.5gm BD with hot water for 45days) and *ERANDAI THAILAM*(External medicine), if you wish to stay in the
In Patient ward VARMAM Treatment 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 confidential. I will ask you few questions through a questionnaire.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.V.Rubini PG Scholar, Ph.no:8939562365 cum principal investigator of this study, attached to National Institute of Siddha, Chennai-47. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, for rights and participation in the study.

தகவல் படிவம்

அழல்கீல் வாயு நோய்க்கான சித்த மருந்துகளின் ***கண்டாத்திரி சூரணம்*** (உள் மருந்து) மற்றும் ***ஏரண்டைத் தைலம்*** (வெளி மருந்து) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர் : மரு. வீ.ரூபினி

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்
தாம்பரம் சானட்டோரியம்
சென்னை- 47

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர் மரு. வீ.ரூபினி) **அழல்கீல் வாயு** என்னும் நோய்க்கான மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

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

இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக கண்டாத்திரி சூரணம் 1.5 கிராம் வெந்நீரில் 2 வேளை (காலை மாலை) உணவுக்குப் பின் 48 நாட்களுக்கு உட்கொள்ள வேண்டும். வெளி மருந்தாக ஏரண்டைத் தைலம் 48 நாட்களுக்கு நோயுள்ள இடங்களில் வெளியே தடவ வேண்டும். வெளி நோயாளர் 7 நாட்களுக்கு ஒருமுறை மருத்துவமனைக்கு வரவேண்டும். உள் நோயாளியாக தங்க விருப்பம் தெரிவிக்கும் பட்சத்தில் நோய்க்குத் தகுந்த சிகிச்சை அளிக்கப்படும்.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன். இதில் பயணப்படி முதலிய எந்த உதவி தொகையும் வழங்கப்பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க மாற்று சிகிச்சை அளிக்கப்படும். இந்த ஆராய்ச்சியில் தங்களை உட்படுத்திய பிறகு உங்களுக்கு விருப்பமில்லையெனில் எப்போது வேண்டுமானாலும் விலகி கொள்ள முழு உரிமை உள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மை பற்றியும் முதன்மை ஆராய்ச்சியாளரான மரு. வீ.ரூபினி (பட்ட மேற் படிப்பாளர் சிறப்பு மருத்துவ பிரிவு) அணுகவும். கைப்பேசி எண் 8939562365 மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறப்பட்டுள்ளது.

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Principal Investigator: Dr.V.Rubini

CONSENT FORM - 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

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் **அழல்கீல் வாயு** என்னும் நோயின் ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

<u>நோயாளியின் ஒப்புதல்</u>

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.

நான் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையைத் தெரிந்திருக்கின்றேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு **அழல்கீல் வாயு** என்னும் நோய்க்கு சகலவாத சூரணம் (உள் மருந்து) மற்றும் நொச்சி எண்ணெய் (வெளி மருந்து) மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

தேதி: **சாட்சிக்காரர் கையொப்பம்:**

இடம்: **பெயர்:**

உறவுமுறை:

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

DEPARTMENT OF SIRAPPU MARUTHUVAM

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Principal Investigator: Dr.V.Rubini

FORM VII - WITHDRAWAL FORM

1. SERIAL NO OF THE CASE: ……

2. OP / IP NO: .....

3. NAME: ……

4.AGE: ……

5.GENDER:.....

6. DATE OF TRIAL COMMENCEMENT: ……...

7. DATE OF WITHDRAWAL FROM TRIAL: ……..

8. 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
Development of adverse event:	Yes/No

(If YES, give the details of adverse reaction in Form VII -B – Adverse Reaction Form / Pharmaco Vigilance Form)

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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Principal Investigator: Dr.V.Rubini

FORM - VIII DIETARY ADVICE FORM

சேர்க்க கூடிய உணவுகள்	**தவிர்க்க வேண்டியவைகள்**
காய்கள் (Vegetables): கத்தரிப்பிஞ்சு (Unripe brinjal) முருங்கைப்பிஞ்சு (Unripe drumstick) அவரைப்பிஞ்சு (Unripe Dolichos bean) **கீரைகள்(Greens):** பொன்னாங்கண்ணி (Sessile plant [*Alternanthera sessilis*]) மூக்கிரட்டை (Hog weed [*Boerhaavia diffusa*]) தூதுவேளை (Climbing brinjal [*Solanum trilobatum*]) முருங்கைக்கீரை (Leaves of Drumstick [*Moringa oleifera*]) கறிவேப்பிலை (Curry leaf [*Murraya koenigii*]) முடக்கறுத்தான் (Winter cherry [*Cardiospermum halicacabum*]) அறுகீரை (*Amaranthus tristis*) கரிசாலை (trailing eclipta [Eclipta prostrate]) **பழங்கள்(Fruits):** மாதுளை (Pomegranate) ஆப்பிள் (Apple)/ பப்பாளி (Papaya) ஆரஞ்சு (Orange)/ பேரீச்சை (Dates) அத்தி (Fig) நாவல் (Jambul [*Syzygium cumini*]) **அசைவம் (Non-vegetarian diet):** வெள்ளாட்டுக்கறி (Meat) காடை (Quail), இறால்மீன் (Prawn)	சுரை (Bottle gourd) பூசணி (Pumpkin) வெள்ளரிக்காய் (Cucumber) புடலை (Snake gourd) பீர்க்கு (Ridged gourd) உளுந்து (Black gram) மொச்சை (Indian butter Bean) காராமணி (Cow gram) கொள்ளு (Horse gram) கடுகு (Mustard) எண்ணெய் (Gingelly oil) புளிப்பு (Sour) உப்பு (Salt) வாயுப் பொருட்கள் (Vatha diet) உருளைக் கிழங்கு (Potato) வாழைக் காய் (Plantain) புகையிலை (Tobacco) மது அருந்துதல் (Alcohol) பெண்போகம் (இச்சா பத்தியம்) [Sexual intercourse]

மருத்துவ அறிவுரை:

ஈரமில்லாத் தரையிலும், படுக்கையிலும் படுத்தல் வேண்டும், குளிர் காற்று படும்படியான இடத்தில் இருப்பதைத் தவிர்க்கவும். உடல் அதிக எடை இருப்பின் எடையைக் குறைக்க வேண்டும். அதிக தூரம் நடத்தல், அதிக நேரம் நிற்றல் தவிர்க்கவும்

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DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"KANDATHIRI CHOORANAM"*** (INTERNAL) AND **"*ERANDAI THAILAM"*** (EXTERNAL) IN THE TREATMENT OF ***"AZHAL KEEL VAYU"*** (OSTEOARTHRITIS OF KNEE JOINT) WITH AND WITHOUT VARMAM THERAPY.

Principal Investigator: Dr.V.Rubini

FORM –IX ADVERSE REACTION FORM

SERIAL NO:

OP/IP NO:

NAME: **AGE:** **GENDER:**

DATE OF TRIAL COMMENCEMENT:

DATE OF THE ADVERSE REACTION OCCUR:

DESCRIPTION OF ADVERSE REACTION:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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