# COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUGS "VITHU RASA MEZHUGU" (INTERNALLY) AND MURIVENNAI (EXTERNALLY) IN THE TREATMENT OF MUZHANGAL MOOTU SAVVU KAYANGAL (KNEELIGAMENT INJURY) WITH AND WITH OUT VARMAM THERAPY"

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**DECLARATION BY THE CANDIDATE** 

I hereby declare that this dissertation entitled "Comparative clinical trial of Siddha

drugs "Vithu Rasa Mezhugu" (Internally) and "Murivennai" (Externally) in the treatment

of "Muzhangal Mootu Savvu Kayangal" (Knee-Ligament Injury) with and without

Varmam Therapy is a bonafide and genuine research work carried out by me under the

guidance of Dr.V. Mahalakshmi, M.D(s)., Ph.D. Associate Professor, 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.

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**Signature of the Candidate** 

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**BONAFIED CERTIFICATE** 

Certified that I have gone through the dissertation submitted by Dr.M. Monika

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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

Siddha system of medicine is a potent and unique indigenous system of medicine, which deals with the disease of men efficiently with the knowledge of both subtle and also the gross material body.

The origin of the siddha system dates back BC 10000 – BC 4000, according to Thiru. T. V. Sambasivampillai siddha medical dictionary. The word siddha comes from the word siddhi.Siddhi means knowledge or wisdom. The ultimate aim of siddha is to attained perfection or heavenly bliss.

Siddha system of medicine classifies diseases into 4448 types. According to this system of medicines, the human body is made up on three humors – Vali, Azhal, Iyyam in normal healthy condition ratio between them being 1:½: ¼. When the normal ratio of Sthese humors – Vali, Azhal, Iyyam is disturbed, disease will occur. The factors which affect this equilibrium are environment, climatic conditions, diet and abnormal physical activities etc.

As per "Varma odivu murivu maruthuvam", mootu kayangal is classified into 3 types. One such type is *Muzhangal mootu savvu kayangal*. Muzhangal mootu savvu kayangal has a symptoms of pain and swelling present in joints, difficulty in flexion and extension.

The human physical body comprises many joints, which extends small to large in nature for the purpose of fine to vast movements. Some joints is very important for weight bearing and locomotion. A joint encompasses bony parts, ligaments, tendons and synovial membranes and fluids. The knee joint is an imperative for weight bearing and locomotion and also take the necessary parts in sports activity. Ligament injury- knee joint is an annoying and painful condition that limits the functions of the joint. There is a pain and tenderness in the knee joints during standing and walking. So, this condition *Muzhangal mootu savvu kayangal* may be correlated to Ligament injury-knee joint.

A relatively high incidence of ligamentous disruptions has been noted in obese and loose joined people, particularly from exposure to athletic activity. Motor vehicular accidents especially involving motorcycles, are common causes of knee ligament disruptions. Popping sensation felt or heard at the time of injury signifies ligamentous injury. Patient may present with pain, swelling of the knee could be either due to hemarthrosis or traumatic synovitis, history of locking or instability in the knee joint.

Sports-related injury knee injuries occur commonly in athletes. In 2016 survey, Anterior cruciate ligament injury was the most common injury and was noted in 86.5% of knee injuries (n=314: complete ACL tear- 287 and partial ACL tear- 27). Meniscal injury was the second most common knee injry seen in 78.24% of the knee injuries. Collateral ligament injuries were noted in 133 knees with MCL injury seen in 25.62% of the knees (n=93) and LCL injuries seen in 11.01% (n=40). Posterior ligament injuries were the least observed injuries accounting for 2.76% of the injuries (n=10).

In modern system of medicine, only recourse for the ligament injury is surgery. Siddha system has good ailments to take ligament injuries especially through external therapy and *Varmam* therapy.

Now a days, considerably more number of patients reporting daily for the treatment for *Muzhangal mootu savvu kayangal (Ligament injury – knee joint)* in Ayothidoss Pandithar Hospital, National Institute of Siddha. The ingredients of *Vithu rasa mezhugu* has pharmacological activities like Analgesic and Anti-inflammatory activities. Hence the author has chosen this disease with the trial drug "*Vithu Rasa Mezhugu*" (Internal) and "*MurivuEnnai*" (External).

#### AIM AND OBJECTIVE

#### **AIM**

To evaluate the therapeutic efficacy of siddha drugs *Vithu Rasa Mezhugu* (Internal) and *Murivu ennai* (External) in reducing the pain and restricted movements in the treatment of *Muzhangal mootu savvu kayangal* (Ligament injury-knee joint) with and without varmam therapy through clinical study.

#### PRIMARY OBJECTIVE:

To evaluate the therapeutic efficacy of siddha drugs *Vithu Rasa Mezhugu*(Internal) and *Murivu ennai* (External) in reducing the pain and restricted movements in the treatment of *Muzhangal mootu savvu kayangal* (Ligament injury-knee joint) with and without varmam through clinical study.

#### **SECONDARY OBJECTIVE:**

- 1) To study the pattern of *Naadi*
- 2) To study the pattern of *Neikuri*
- 3) To analyze the distribution of *Udal thathukal*
- 4) Biochemical analysis

#### SIDDHA ASPECT

#### MUZHANGAL MOOTU SAVVU KAYANGAL

In Siddha literature *Muzhangal mootu savvu kayangal(MMSK)* described under Vaatha diseases. The Mootu kayangal is the general term that includes all kinds injuries to the joint.

Description of the nomenclature

Muzhangal mootu savvu kayangal = Muzhangal mootu + savvu +

kayangal

Muzhangal mootu = Knee joint

Savvu = Ligaments

Kayangal = Injuries

Thejoint is initially affected by vitiated *vaatham*, *Pitham and Kabam* accompany later.

#### TYPES OF MOOTU KAYANGAL:

There are three types of mootu kayangal which are mentioned in the textbook "VARMA ODIVU MURIVU MARAUTHUVAM". MMSK is one among 3 types of Mootu kayangal. The 3 types are mentioned below

- 1. Savvu kayangal(Injuries to ligaments)
- **2.** Mooturai kayangal(Injuries to synovium)
- 3. Naanuraipai kayangal(Injuries to bursa)

#### வாதத்தின் இருப்பிடம்

"நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய் நாடிக்குக் கீழென்று நவிலலாகும்"

#### வாதம் வாழுமிடம்:

அபானம், மலம், இடகலை, உந்தியின் கீழ் மூலம், காமக்கொடி, இடுப்பு எலும்பு, தோல், நரம்புக்கூட்டம், கீல்கள், மயிர்க்கால்கள், ஊன்.

Muzhangal mootu savvu kayangal is a clinical condition which occurs when ligaments around the knee joint is either stretched, partially torn or completely torn. Joints (கீல்கள்) are one of the places where "Vaatham" resides.

#### **AETIOLOGY:**

#### **1. DIET:**

Vaatha disease is caused due to the following reasons:

#### According to the text 'Sababathi Kaiyedu'

"வளி தரு காய்கிழங்கு வரைவிலா தமிலல் கோழை புளி தயிர் போன்மிகுக்கு முறையிலா வுண்டி கோடல் குளிர்தரு வளியிற் றேகங் குனிப்புற வுலவல் பெண்டிர் குளிதரு மயக்கம் பெற்றோர் கடிசெயல் கருவியாமல்."

- Excessive intake of tubers
- Excessive intake of chill foods just like the curd.
- Wandering in chill air in evening time
- Getting drenched in rain
- Living in hilly region
- Excessive sexual indulgence.
- Heredity.
- Excessive intake of bitter, astringent pungent.
- intake of vaatha food substance like varagu, thinai
- Altered sleep pattern also contribute to Vaatha disease.

#### 2. HABITS:

"தானென்ற கைப்பொடு துவர்ப்புவர்ப்பு சாதகமாய் மிஞ்சுகிலும் சமைத்த அன்னம் ஆனென்ற ஆறினது புசித்தாலும் ஆகாசத் தேற்ற நீர் குடித்தலாலும் யானென்ற பகலுறக்கம் இராவிழிப்புப் பட்டினியே மிகவுறுதல் பாரமெய்தல் தேனென்ற மொழியார் மேல் சிந்தையாதல் சீக்கிரமாய் வாதமது செனிக்குந்தானே"

- யூகிமுனி வைத்திய சிந்தாமணி
- Intake of food rich in bitter, sour and pungent in taste
- Intake of cold and old foods
- Sleep in day time.
- Lack of sleep
- Excessive starvation
- Weight lifting
- Increased sexual indulgence
- These are the factors that disturbs & increase vaatham in our body

# 3. INVOLVEMENT OF MUKKUTRAM IE VAATHAM, PITHAM AND KABAM:

- Viyanan and samanan are affected in Vaatham. Due to pain present in knee joints.
- In Pitham, Sathaga pitham is affected. Due to difficulty in performing daily activities.
- Santhigam is affected in Iyyam. Due to pain and crepitation present in knee joints.

#### 6. CHARACTERISTIC FEATURES OF VAATHAM:

"வாதமது கதித்த போது வாயுமெழும்புங் கண்டீர் வாதமே கதித்தபோது வாயுவு வந்திடுஞ் சந்நிதோடம் வாதமே கதித்தபோது வந்திடும் வியாதி மேலும் வாதமே கதித்தபோது வல்லுடல் மெலிந்து கொல்லும்" – அகத்தியர் சிகிச்சாரத்தின தீபம் When the vaatham is increased from their normal level causes sanni and weight loss leads to death.

"வாத வீறு அன்னமிரங்காது கடுப்புண்டாம் வண்ணமுண்டாம் மோதுகட்கு ரோகம் சுரமுண்டா மிருமலுமா முறங்காதென்றும் ஓதரிய வாதமனலாகு நடுக்கமுண்டாம் பொருள் களயர்ந்த தீதனவே நரம்பித்து சந்துகள் தோறுங்கடக்குந் தினமுந்தானே"

- தேரையர் வாகடம்

When the Vaatha kuttram aggravates it will produce the following signs and symptoms:

- loss of appetite
- excruciating pain
- fever
- Defect in the micturation and defecation
- loss of sleep
- shivering of the body
- nervous weakness
- Joint pain.

#### SITES OF VAATHAM

"நெளிந்திட்ட வாதமடா நத்தைப் பற்றி நிறைந்திடையச் சேர்ந்துந்திக் கீழே நின்று குளிந்திட்ட மூலமதூடெழுந்து காமக் கொடியிடையைப் பற்றியெழுங் குணத்தப்பாரே குணமான வெழும்பைமெற் றொக்கை நாடி நிணமான பொருந்திடமும் ரோமக் காலும் நிறைவாகி மாங்கிசமெல் லாம்பரந்து கால்கட்டி வாதமெங்குங் கலக்குந் தானே"

- வைத்திய சதகம்

According to vaithiya sathagam, vaatham dwells in the following places: Umbilicus, rectum, faecal matters, abdomen, anus, bones, hipjoints, skin, navel plexus, Joints, Hair follicles and muscles.

#### PROPERTIES OF VAATHAM:

Vaatham helps the following function in our body

- It is the main vital humour for the function of 7 UDALKATTUGAL
- Helps to do all activities
- It stimulate and accelerate 5 PULANGAL

#### Natural properties of Vaatham: [Ref: Noi Nadal part-1]

- 1. Functioning of the "Seven Udal Kattukal" uniformly
- 2. Protection and strengthening of the five sensory organs (Imporigal)
- 3. Giving briskness
- 4. Expiration and Inspiration
- 5. Regulation of the "Fourteen Physiological Reflexes" (Vegam)
- **6.** Functioning of the mind, thoughts and body

#### **DIAGNOSIS IN SIDDHA:**

In siddha system of medicine diagnosis of a disease is very important.

#### Piniyari muraigal (Method of Diagnosis) is based upon three main principles,

- 1. Poriyal Arithal (Examination of Sensory Organs)
- 2. Pulanal Arithal (Examination of Sensory Functions)
- 3. Vinaathal (interrogation)

#### 1. PORIYAL ARITHAL (Examination of Sensory Organs):

#### PORI – SENSE ORGANS

"Poriyal arithal" means examining the "Pori" of the patient by the "Pori" of the physician for proper diagnosis.

Pori is considered as the "Five sense organs" of perception namely,

- 1. Mei (Skin)
- 2. Vai (Tongue)
- 3. Kan (Eye)
- 4. Mookku (Nose)
- 5. Sevi (Ear)

#### 2. PULANAL ARITHAL (Examination of Sensory Functions):

#### PULAN - SENSE

Pulanal arithal means examining the "Pulan" of the patient by the "Pulan" of Physician.

Pulan are five senses. They are,

- 1. Smell
- 2. Taste
- 3. Vision
- 4. Sensation of touch
- 5. Hearing

#### 3. VINAATHAL (Interrogation):

Vinaathal is gathering information regarding the history of disease, its clinical features, major complaints, duration of illness etc., from the patient or his/her close relatives useful when the patient is not in a position to speak or in the case of a child.

#### **ENVAGAI THERVUGAL (Eights Folds of Examination):**

It is a unique method of diagnosis in Siddha system of medicine. They are clearly explained by Siddhar Theraiyar;

"நாடி ஸ்பரிசம் நா நிறம் மொழி விழி மலம் மூத்திரமிவை மருத்துவராயுதம்"

- தேரையர்

#### 1. Naadi (Pulse):

"திருத்தமாம் வாதத்தோடே தீங்கோடு பித்தம் சேரிற் பொருத்துகள் தோறும் நொந்து போதவே பிடிக்கும்" - நோயின் சாரம்

"வாட்டிடும் சேத்துமத்தில் வந்திடும் வாதமாகில் நாட்டிய கால்கள் போல நரம்பெல்லாம் வலித்து நிற்கும்" - அகத்தியர் நாடி

"சொல்லிய ஐயத்தோடே பித்தமுங் கூடிற் றானால் சலலியம் போலக் குத்தும் மைந்தனே எலும்பும் தோலும்" - காவிய நாடி

- 2. When Pitham gets vitiation it accompany with Vaatham and causes pain in every joints
- 3. When Kabam and Vaatham are vitiated pain occurs in the nerves and lower extremities.
- 4. When Pitham vitiated with Kabam it results in stabbing pain in bones and joints.

In *MMSK* the following Naadi can be seen commonly: Vaathapitham, Vaathakabam, Pithavaatham, Pithakabam, Kabavaatham.

#### 2. Sparism (Sensation to touch):

In MMSK warmth noticed over the affected joint.

#### 3. Naa (Tongue):

In MMSK no abnormality is seen in Naa.

#### 4. Niram (Colour):

In *MMSK* no abnormality is seen in Niram. The skin complexion is used to diagnose the body constitution of the patient.

#### 5. Mozhi (Voice)

It constitutes high, low-pitched voice, nasal speech, hoarseness of voice slurring and incoherent speech etc. In *MMSK* no abnormatlities are seen normally.

#### 6. Vizhi (Eyes):

Both motor and sensory disturbance of eye are noticed. Redness of eyes, paleness, excessive lacrimation, swelling, corneal ulcers, sunken eyes may be noted for. In *MMSK* no abnormatlities are seen normally. In anaemic patients pale conjunctiva may be noted.

#### 7. Malam (Faeces):

• Vaatha type: Black coloured stools with constipation.

• Pitha type: Loose stools with yellowish red colour

• Kaba type: White coloured stools with mucous

• Thontha type: Stools possess some of the features of two humours.

In MMSK constipation was reported in some cases.

#### 8. Moothiram:

Neerkuri and Neikuri (Oil on urine sign) are special diagnostic methods regarding urine (Moothiram).

#### A.NEERKURI (Physical examination of urine):

"அருந்து மாறிரதமும் அவிரோதமதாய் அகல அலர்தல் அகாலவூன் தவிர்ந்தழற் குற்றள வருந்தி உறங்கி வைகைறை ஆடிக் கலசத் தாவியே காதுபெய் தோரு முகூர்த்தக் கனலக் குட்படு நீரின் நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே" - சித்த மருத்துவாங்கச் சுருக்கம்

Prior to the day of urine examination the patient is instructed to take a balanced diet and quantities of food must be proportionate to his routine intake. The patient should have no sound sleep. After waking up in the morning, the first urine voided is collected in a clear wide mouthed glass bowel and is subjected to analysis of "Neerkkuri and Neikkuri" within 1½ hour.

"வந்த நீர்க்கரி எடை நுரை எஞ்சலென் றைந்திய லுளவை யறைகுது முறையெ"

- சித்த மருத்துவாங்கச் சுருக்கம்

Voided urine has the following characters

1. Niram - Colour

2. Edai - Specific Gravity

3. Manam - Smell

4. Nurai - Frothy nature

5. Enjal - Deposits

Apart from these, the frequency of urination, abnormal constituents, such as sugar, protein, presence of blood, pus, also to be found out In *MMSK* patient straw coloured urine was noticed.

#### B. NEIKKURI (Oil on urine sign):

The process of dropped gingely oil indication

"நிறக்குறிக் குரைத்த நிருமண நீரிற் சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்

னின்றதிவலை போம் நெறிவிழியறிவும் சென்றது புகலுஞ் செய்தியை யுணரே" -நோய் நாடல் நோய் முதல் நாடல் திரட்டு-பாகம் 1

The collected specimen was examined by the following method. The collected urine specimen is kept in a glass bowel and observed under direct sunlight without shaking the vessel. Then drip one drop of gingely oil and observe the spreading pattern and concludes as follows,

"அரவென நீண்டின அக்தே வாதம் ஆழிபோற் பரவின் அக்தே பித்தம் முத்தொத்து நிற்கின் மொழிவதென் கபமே அரவில் ஆழியும் ஆழியில் அரவும் அரவின் முத்தும் ஆழியில் முத்தும்"

-நோய் நாடல் நோய் முதல் நாடல் திரட்டு-பாகம் 1

- When the oil drops lengthens like a snake it indicates 'Vaatha Neer'
- When the oil drops spreads like a ring it indicates 'Pitha Neer'
- When the oil drops remains that of pearl it indicates' Kaba Neer'

#### **UDAL KATTUGAL (Body Constituents):**

In MMSK, Saaram, Kozhuppu, Moolai and Enbu thathukkal are commonly affected.

**1.** Saaram : Weakness, pain in knee joints

**2.** Kozhuppu : Morning stiffness occurs in affected knee joints

**3.** Enbu : Pain occurring in affected knee joints& crepitations

**4.** Moolai : Inflammation, swelling etc

#### **MUKKUTRA VERUPAADU (PATHOGENESIS)**

Human body is influenced by Mukkutrams ie Vaatham, Pitham and Kabam. They are responsible for normal physiological conditions of the body.

#### **VAATHAM (Bio Energy of Movements):**

Vaatham is mainly responsible for proper loco-motor functions. Bones and joints are considered to be the main location of vaatham. In *MMSK* the vaatha kutram is mainly affected followed by Pitham and Kabam. This produces the following signs and symptoms,

 Vitiated viyanan leads to pain and difficulty in movements. Vitiated abanan leads to constipation.

- Inflammatory changes of the joints, redness and warmth are developed due to vitiated pitham.
- Sathaga pitham gets affected hindering the loco motor functions
- Along with vaatham, kabam is also vitiated, santhikam is affected and this leads to Abnormality in joint movements
- 1. In *MMSK* Abanan is affected and so constipation is produced.
- 2. Viyanan is affected it renders difficulty in movements of the knee joints.
- 3. Samanan is also affected because disturbed state of other Vaayus.

#### **PITHAM (Bio Energy of Fire):**

In *MMSK*, Sathaga Pitham affected and produces difficulty in walking, climbing upstairs, squatting and sitting postures.

#### **KABAM (Bio Energy of Water):**

Kaba kutram stabilizes and maintains the movements of the joints and gives lubrications to all movements.

In *MMSK* Santhigam is affected and produce difficulty in movements of the knee joints.

#### NOI KANIPPU VIVAATHAM (DIFFERENTIAL DIAGNOSIS):

Muzhangal mootu savvu kayangal is differentiated from the followings diseases,

AZHAL KEEL VAAYU: It is characterized by pain in the joints associated
with effusions of joint fluid and swelling, warmth, tenderness and restricted joint
movements, especially in knee joint asymmetrically, morning stiffness, crackling
sound present when the joint is moved etc.

#### LINE OF TREATMENT:

In Siddha system the main aim of the treatment is to cure Udarpini (due to Mukkuttram) and Manapini (due to changes in Mukkunam). Treatment is not only for perfect healing but also for the prevention and rejuvenation.

It is essential to know the disease, the aetiology, the nature of the patient, severity of the illness, the seasons and the time of occurrence must be observed clearly.

Line of treatment is as follows:

- 1. Neekkam (Treatment)
- 2. Niraivu (Rejuvenation)
- 3. Kaapu (Prevention)

#### 1) NEEKKAM (Treatment in Siddha):

Siddha system of Medicine is based on Mukkutra Theory. Hence the treatment is mainly aimed to bring the vitiation of three humours to equilibrium state and thereby restoring the physiological condition of the seven Thathus.

The three Humours organise, regularise and integrate the body structure and their functions. They are always kept in a state of balance by thought, word, deed and food. Any imbalance will lead to disease. The imbalanced humours are balanced by administrating purgatives or emetics or application of Anjanam (application on eyes) and followed by the appropriate systemic therapy by giving drugs.

The trial drugs Vithu rasa mezhugu – 65mg twice a day given with palm jaggery after food. Murivuennai was applied externally.

#### 2) NIRAIVU (Rejuvenation):

Physical, psychological, social and economic rehabilitation and reassurance of individuals is known as Niraivu. The word literally means the power of securing the body from the effect ofage. According to Siddhars science rejuvenation does not necessarily mean restoring the oldto youth for it may simply mean the maintenance of youth without reaching the old age. So rejuvenation is a means for prolonging life & forms a part of immortality.

- T.V. Sambasivam pillai dict

#### 3. KAPPU (PREVENTION):

The prevention methods for *MMSK* are as follows:

- Control the body weight by diet and exercise.
- Modify the nature of work which gives stress to a particular joint. e.g. Avoid prolonged standing and long distance walking.
- Avoid excessive intake of sour, astringent and bitter tasted foods.

#### 4) DIETARY RESTRICTIONS:

In siddha system of medicine the importance of dietary habits also emphasiszed for the diseases management and prevention. This line is well understood in these verses,

''உணவே மருந்து மருந்தே உணவு''

"மருந்தென வேண்டாவாம் யாக்கைக்கு அருந்தியது அற்றது போற்றி உணின்"

-திருக்குறள்

In diseased condition diet restrictions or paththiyam are strictly followed to increase the effectiveness of medicine, and to reducing the severity of diseases. This is given in the following verse,

"பத்தியத்தினாலே பலன் உண்டாகும் மருந்து பத்தியங்கள் போனால் பலன்போகும்-பத்தியத்தில் பத்தியமே வெற்றிதரும் பண்டிதர்க்கு ஆதலினால் பத்தியமே உத்தியென்று பார்"

- தேரையர் வெண்பா

## இச்சா பத்தியத்தில் நீக்கும் பொருட்கள்:

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

- சித்த மருத்துவாங்கச் சுருக்கம்

கடுகு, எள்நெய், கல்யாணபூசணிக்காய், கள், கடலை, தேங்காய், மாங்காய், பலா, காயம், உள்ளிபூண்டு, கொள், புகையிலை, பெண்கள் சேர்க்கை, பாகல், அகத்தி இவைகளை இச்சா பத்தியத்தில் நீக்கவேண்டும்.

"புளிதுவர் விஞ்சும் கறியால் பூரிக்கும் வாதம்" - நோய் நாடல் நோய் முதல் நாடல் திரட்டு

## மருத்துவ அறிவுரை:

- புளிப்பு, துவர்ப்பு சுவையுள்ள உணவு வகைகளை நீக்க வேண்டும்
- 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.

#### 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 (shin bone), fibula (outer shin bone) and patella (kneecap). The main movements of the knee joint occur between the femur, patella and tibia. Each are covered in articular cartilage which is an extremely hard, smooth substance designed to decrease the frictional forces as movements occurs 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.

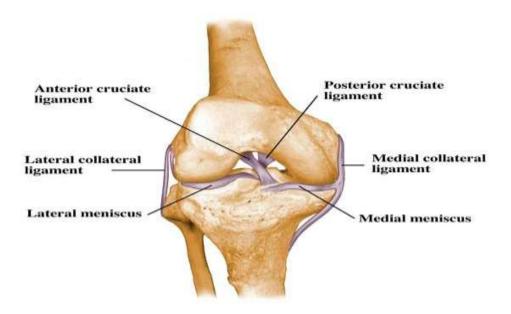
#### Ligaments of the knee joint:

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



#### 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.

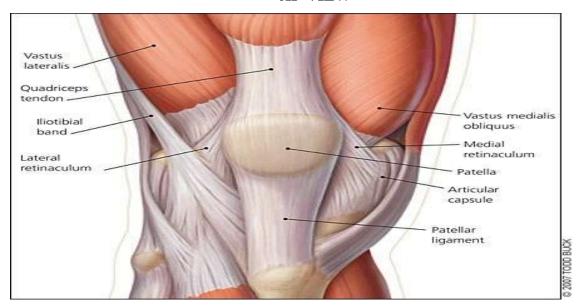
#### Quadriceps muscle:

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.

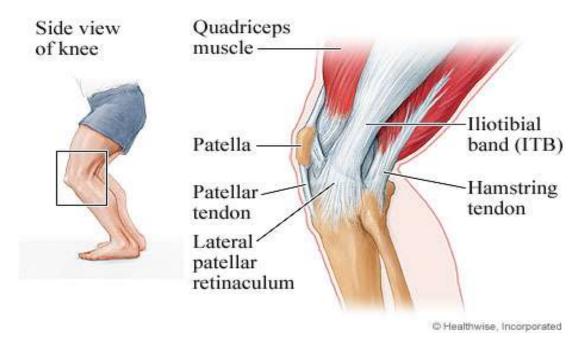
#### Hamstrings muscle:

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

# MUSCLES AROUND THE KNEE JOINT AP-VIEW

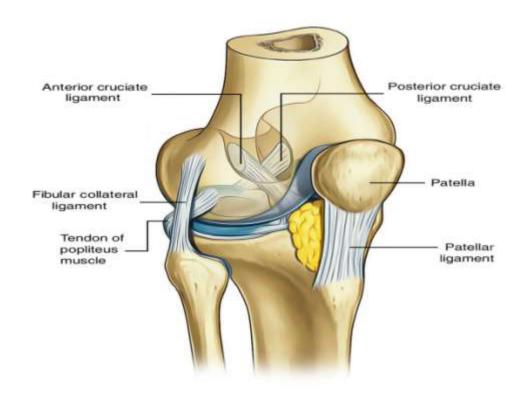


#### LATERAL VIEW



#### **KNEE JOINT-LIGAMENT INJURY:**

#### **INTRODUCTION:**



With modern high-speed vehicular trauma and increasing athletic participation, both competitive recreational, traumatic lesions of the ligaments about the knee are becoming increasingly more common. Knee stability depends on numerous factors, including the mechanical axes of the joint, the bony contours, the intraarticular stabilizers (the menisci and cruciate ligaments), and extraarticular stabilizers (the synovium, capsular ligaments, collateral ligaments, and musculotendinous units).

The goal of treatment of traumatic lesions of the ligaments is restoration of the anatomy and stability to as near preinjury status as possible. Failure to accomplish this results in ajoint increasingly susceptible to more damage from the normal living and trivial trauma. Also, failure to restore normal knee stability exposes other structures such as the menisci, the cruciate ligaments, and the joint surfaces to additional injury as well as markedly reducing the functional capabilities and activities of the individual. The result often is severe degenerative arthritis.

#### **EPEDEMIOLOGY:**

With an incidence of about 30 cases of ACL injury per 100 000 people per year, any district general hospital should have a sufficient throughput to provide a surgeon with enough patients to maintain and improve his/her operative skills. A hospital with a catchment area of 400000 population population will have about two fresh ACL injuries a week presenting through their casualty department.

#### Age and sex related prevalence:

In 1995, female racers were 2.3 times more likely to have sustained a knee injury than male racers. More impressively, one in five female alpine racers (22%) reported an ACL distruption, and female were 3.1 times more to sustain an ACL injury in comparison to their male counterparts. Of the athletes who had surgery to reconstruct their ACL, approximately one-third (36%) required subsequent surgery to the same knee. One in five (22%) ACL reconstructions failed, requiring additional surgery to the ACL. Females reported a higher rate of reinjury to an ACL graft than males (27% vs. 13%).

#### **ETIOLOGY:**

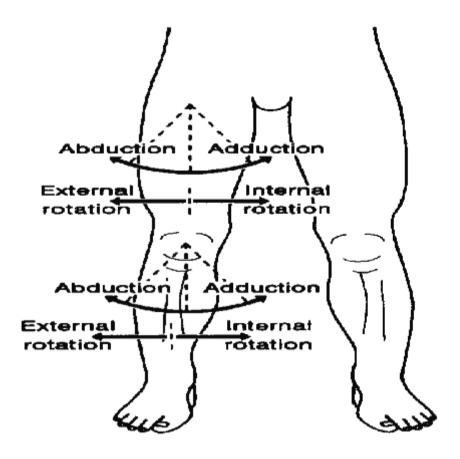
Knee ligaments are often injured in athletic activities, especially when contact is a feature, as in American football. Skiing, ice hockey, gymnastics, and other sports may also produce enough suddn stress to disrupt knee ligaments. In India wrestling and gymnastics activities are the main cause of injury to ligaments.

Motor vehicular accidents, especially involving motorcycles, are common causes knee ligament disruptions.

#### **MECHANISM:**

Palmer describes four mechanisms capable of producing disruptions of the ligamentous structures about the knee.

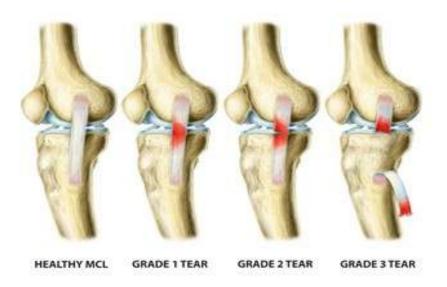
- 1. Abduction, flexion, and internal rotation of the femur on the tibia.
- 2. Adduction, flexion, and external rotation of the femur on the tibia.
- 3. Hyperextension
- 4. Anteroposterior displacement.



By far the most common mechanism is abduction, flexion and internal rotation of the femur on the tibia when the weight-bearing leg of an athlete is struck from the lateral aspect by an opponent. The mechanism results in an abduction and flexion force on the knee, and the femur is rotated internally by the shift of the body weight on the fixed tibia. This mechanism produces injury on the medial side of the knee, the severity of which depends on the magnitude and dissipation of the applied force. The mechanism of adduction, flexion, and external rotation of the femur on the tibia is much less common and produces the primary disruption laterally. Again the severity of the disruption depends on the mangnitude and dissipation of the force applied. Force directed to the anterior to the aspect of the extended knee, a hyperextension mechanism, usually injuries the anterior cruciate ligament (ACL), and if the force continues or is severe, stretching and disruption of the posterior capsule and posterior cruciate ligament (PCL) may result. Anteroposterior forces applied to either the femur or the tibia, such as the tibia striking the dashboard, may produce injuries to either the anterior or the posterior cruciate ligament depending on the tibial displacement.

The severity of the lesion depends on the direction, magnitude, and dissipation of the force. When abduction, flexion, and internal rotation of the femur on the tibia occur, the medial supporting structures, the tibial collateral ligament, and medial capsular ligament are the initial structures injured. If the force is sufficient magnitude, and ACL also is often torn. The medial meniscus may be trapped between the condyles of the femur and the tibia, and it may be torn at its periphery as the media structures tear, thus, producing "the unhappy triad" of O'Donoghue. Conversely with adduction, flexion and external rotation of the femur on the tibia, the fibular collateral ligament usually is initially disrupted and depending on the magnitude of the trauma and the displacement, is followed by the capsular ligaments, the arcuate ligament complex, popliteus, the iliotibial band, the biceps femoris, and not infrequently the common peroneal nerve and one or both cruciate ligament.

#### **CLASSIFICATION:**



A sprain is defined as on injury limited to ligaments (connective tissue attaching bone to bone) and a strain as a stretching injury of muscle or its tendionous attachment to bone.

Sprains are classified into three degrees of severity. A first-degree sprain of a igaments is defined as a tear of a minimum number of fibres of the ligament with localized tenderness but no instability.

A second-degree sprain as a disruption of more ligamentous fibres with more loss of function and more joint reaction with mild to moderate instability.

A third-degree sprain as a complete disruption of the ligament with resultant marked instability.

These are often classified as mild, moderate and severe for first, second, and third-degree sprains, respectively.

The third-degree sprains, i.e. those demonstrating marked instability, may be further graded depending on the degree of instability demonstrated during stress testing.

A 1-plus instability indicates that the joint surface separate 5mm or less, with 2-plus instability, they separate between 5 and 10mm and with 3-plus instability, they separate 10mm or more. A standardized classification is important for accurate communication, and although it obviously is not always precise, it does provide a workable scale for clinical purposes.

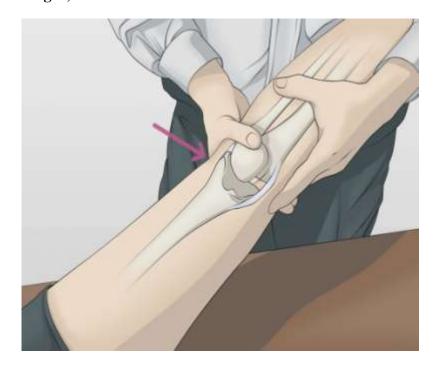
#### **DIAGNOSIS:**

#### **Physical examination:**

Physical examination should be complete, precise, systematic, and carried out as soon after the injury as possible so as to minimize problems of severe swelling, tense effusion, and the related involuntary muscle spasm that make examination and precise diagnosis more difficult.

Areas of eccymosis and large effusions are readily noted, although smaller effusions may require careful palpation. Haemarthrosis suggest rupture of a cruciate ligament, an osteochondral fracture, a peripheral tear in the vascular portion of a meniscus, or a tear in the deep portion of the joint capsule. A nonbloody effusion suggests an irritative synovitis that may be caused by a degenerative meniscus or a chronic process.

#### **Abduction, or valgus, stress test:**



The abduction, or valgus, stress test is performed with the patient supine on the examination table. Abduct the extremity off the side of the table and flex the knee approximately 30 degree. Place one hand about the lateral aspect of the knee and the other supporting the ankle. Gently apply the abduction or valgus stress to the knee, while the hand at the ankle externally rotates the leg slightly.

#### Adduction, or varus, stress test:



The adduction, or varus, stress test is carried out in a manner similar to the valgus stress test, and the test is also performed after xamination of the normal knee. Adduction or varus stress is applied by changing the hand to the medial side of the knee and applying an adduction or varus force. Examnation should be done both in full extension and in 30 degrees of flexion.

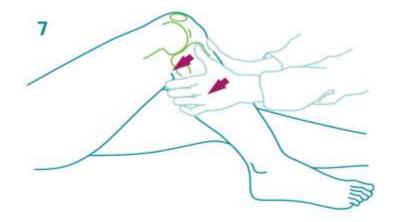
#### **Anterior drawer test:**



With patient supine on the examining table, flex the hip to 45 degrees and the knee to 90 degrees, placing the foot on the tabletop. Sit on the dorsum of the patient's foot to stabilize it, and place both hands behind the knee to feel for relaxation of the hamstring muscles. Then gently and repeatedly pull and push the proximal part of the leg anteriorly and posteriorly, noting the movement of the tibia on the femur. Perform the test in three positions of rotation. Initially perform the test with the tibia in neutral rotation followed by testing in 30 degrees of external rotation.

Internal rotation to 30 degrees may tighten the posterior cruciate enough to obliterate an otherwise positive anterior drawer test. Record the degree of displacement in each position of rotation and compare with the normal knee. Repeat each maneuver at 30 and 60 degrees.

#### Posterior drawer test:



The posterior drawer test with the patient supine, the knee flexed to 90 degrees, and the foot secured to the table by sitting on it. Apply a posterior force on the proximal tibia opposite to but similar to that applied in the performance of the anterior drawer test. Posterior movement of the tibia on the femur demonstrates posterior instability when compared with the normal, indicating PCL tear.

#### **SYMPTOMS:**

- > Popping sensation in the knee
- > Severe pain and discomfort
- Swelling
- > Loss of range of motion
- ➤ Knee stability or buckling
- > Loss of bearing any weight
- ➤ Bleeding within the joints
- > Difficulty in returning to activity

#### **COMPLICATION:**

- ➤ Risk of developing knee osteoarthritis
- > Deterioration of joint cartilage
- > Less range of motion
- **▶** Limping

# **INVESTIGATION:**

a.) Magnetic Resonance Imaging (MRI)

To evaluate the ligamentous and cartilaginous structures of knee.

b.) Arthroscopy:

Direct visualization and palpation of partial ACL tears.

#### **SPECIAL TREATMENTS:**

#### **VARMAM**

Varmam is a science dealing with the impact to innumerable nerve junctions of thehuman body. The changes occurring in the body on being hit at some specific points on thebody directly or indirectly with a particular force is known as varmam. In human body from the head to leg there is numerous numbers of points present called in the name of varmam.

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

In our lifestyle varmam is the major cause for muscular sprain, joint pain and low back pain. It is present in our inner aspect of our body.

In our Siddha literature Varmam is basically divided into two parts

They are

- 1. MEDICINAL ASPECT
- 2. DEFENCE & OFFENCE ASPECT

#### SYNONYMS AND OTHER NAMES OF VARMAM:

Kalam, Adakkam, Marmam, Sutchamam, Vanmam, Yemam, Idu , Karuvi, Kalai, Sarvaathma vazhum veedu, Seevan swasam.

#### **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 (which is normally not done). It is also a science; it helps treat persons from the impact arising from traumatic injuries.

#### **VARMAM AND OTHER MARTIAL ARTS:**

Varmam has also accompanied to other martial arts such as silambam, sword fighting, kalari etc. In these arts, the life energy centers of men are made known to practitioners to enable them to achieve their ends.

#### SIGNS OF LIFE ENERGY CENTERS IF AFFECTED:

Hundreds of life energy centers of human body lie dormant as bones, nerves, veins, muscles, joints and inner organs are found either deep or at the surface of the body.

- Vital lifecenters are dominant on bones and joints.
- Medium life centre on nerves.
- Inner life centers on muscles.

If the life energy centers are traumatized by hit or cut either directly or indirectly, and then whole body is left out of control. In other words the whole body is paralyzed. It is manifested by symptoms like fainting, sprain, swelling, bleeding, shivering, fractures, dislocations or even death.

VARMAMS ARE TOTALLY 108 IN NUMBER.

#### **CLASSIFICATION OF VARMAM**

There are 2 major classifications present in Varmam.

They are classified as below

#### 1. Padu varmam – 12

- 3 is fatal
- 9 is normal

#### 2. Thodu varmam

- 16 is fatal
- 80 is normal

#### **BRANCHES OF VARMAM**

- 1. Vaatha Varmam −9
- 2. Pitha Varmam -45
- 3. Kaba Varmam − 25
- 4. Hand -14
- **5.** Leg 15

**TOTALLY 108 IN NUMBER** 

#### **MAATHIRAI:**

It is the basic unit of varmam technique. It is the force that attacks a person to make symptoms of a particular varmam.

Depending upon the force it divides into

- 1. 1/4 Maathirai otherwise called as EEDU
- 2. 1/2 Maathirai otherwise called as AEMAM
- 3. 3/4 Maathirai otherwise called as KAALAM
- 4. 1 Maathirai otherwise called as VARMAM

# Varmam points to be manipulated in Muzhangal mootu savvu kayangal patients are:

- 1. Kaal Mootu Varmam (Varma Viralalavu Nool)
- 2. Mozhi Poruthu Varmam (Varma Noolalavu Nool)
- 3. Sirattai Varmam (Varma odivu murivu sara soothiram-1200)
- 4. Mootu pathaipu Varmam(Varma Noolalavu Nool)

#### 1. KAAL MOOTTU VARMAM:

களியான மூட்டுவர்மம் குணமேதென்றால் காரணமாய் சிரட்டையது நகண்டு போகும் வெளியாக வருத்தமது சகிக்கொட்டாது வேகமாய் மயக்கமொடு தளர்ச்சையாகும் ஒளியான சிரட்டையதை எடுத்து வைத்து உறப்பான பசையிட்டு சுற்றிக்கெட்டி வளியான கட்டுமுறை செய்து முன்னே வரும் எண்ணெய் விட்டு கைபாகம் பாரே

## SYNONYMS:

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

#### LOCATION:

"தானதிலே முட்டிசைவில் மூட்டு வர்மம்" (வர்ம கண்ணாடி-500)
Located in anterior aspect of knee joint

#### 2. MOZHI PORUTHU VARMAM:

"காலின் சிரட்டைக்கு ஒன்பது விரலினும் வலத்தே களி நரம்பு வர்மம் உள்ளது"

(வர்ம விளக்கம்)

"ஆரப்பா முட்டினகம் அடிநரம்பில் சுளுக்கு வர்மம் அதன் பக்கம் சன்னிவர்மம் சிரட்டை வர்மம்"

(வர்ம நிதானம்)

"திரி நரம்பு கோச்சு வர்மம் : முட்டின் அடியில் நரம்பு மூன்று இந்நரம்புகள் அற்றுபோனால்"

(வர்ம ஆணி)

#### SYNONYMS:

- மொழிபொருத்து வர்மம் (வர்மம் நூலளவு
- சுளிநரம்பு வர்மம்(வர்ம விளக்கம்)
- சுளுக்கு வர்மம்(வர்ம நிதானம்)
- திரி நரம்பு கோச்சு வர்மம்(வர்ம ஆணி)

#### LOCATION:

Located in popliteal fossae

#### 3. SIRATTAI VARMAM:

"விட்டதொரு நாய்தலை வர்ம மதிலிருந்து யிரண்டு விரலின் மேல் சிரட்டை வர்மம் விரித்துச் சொன்னேன்"

(வ.ஒ.மு.சரசூத்திரம்-1200)

"அறைகிறேன் சில்லியதில் சில்லிவர்மம்"

(வர்மசாரி-205)

"வளமான முட்டதிலே சிரட்டை வர்மம்"

(வர்ம நிதானம்-300)

"ஆரப்பா முட்டினகம் அடிநரம்பின் சுளுக்கு வர்மம் அதன் பக்கம் சன்னிவர்மம் சிரட்டை வர்மம்" (வர்ம நிதானம்-300) "முட்டின் மேல் பக்கம் சிரட்டை வர்மம்" (வர்ம ஆணி-108)

#### SYNONYMS:

- சிரட்டை வர்மம்(வ.ஒ.மு.சரசூத்திரம்-1200)
- சில்லி வர்மம்(வர்மசாரி-205)
- முட்டுச் சிரட்டை(வர்ம நூலளவு நூல்)

#### LOCATION:

Located in patella bone.

## 4. MOOTU PATHAI VARMAM:

"ஆரப்பா முட்டினகம் அடி நரம்பில் சுளுக்கு வர்மம் அதன் பக்கம் சன்னிவர்மம் சிரட்டை வர்மம்" (வர்ம நிதானம்-300)

"தானென்ற முட்டின் இருபக்கத்தில் சன்னிவர்மம் தட்டிடிகள் கொண்டால் கால் தளர்ந்திடும்"

(வர்ம நிதானம்-300)

### SYNONYMS:

- பதைப்பு வர்மம்(வர்ம நூலளவுநூல்)
- சன்னி வர்மம்(வர்ம நிதானம்-300)

#### LOCATION:

Situated 6 fingers adjacent to mootu sirattai varmam, in both sides of the legs.

#### MATERIALS AND METHODS

Comparative clinical trial of siddha drug "Vithu rasa mezhugu" (Internal) and "Murivuennai" (External) in the treatment of "Muzhangal mootu savvu kayangal" (Knee joint-Ligamant injury) with and without varmam therapy.

#### **INTERNAL MEDICINE:**

Drug : VITHU RASA MEZHUGU

Reference book : Anubogavaithiyanavaneetham

Page No : 146

Dosage : 65 mg(1/2 kundri)

Adjuvant : Palm jaggery

Duration : 9 days

Edition : Second edition-May 2001

Author : Hakeem P.M.Abdhullasaayabu

Publication : Thamarai Noolagam

**EXTERNAL MEDICINE:** 

Drug : MURIVU ENNAI

Dosage : Q.S

Reference : Varma kannadi-500

Page no : 216

Author : DR.A. Maria joseph B.Sc., M.D., (S)

Publication : G.P.R.Offset printers

#### STANDARD OPERATIVE PROCEDURE

#### **Source of Trial Medicine:**

The required raw drugs for the preparation of *Vithu Rasa Mezhugu* (Internal) and *MurivuEnnai* (External) was purchased from a well reputed country shop and the raw drugs were authenticated by the competent authority (Medicinal Botany and GunapadamDepartment). After that the raw drugs were purified separately and the Medicine was prepared in Gunapadam laboratory - National Institute of Siddha.

#### PREPARATION OF TRIAL DRUGS:

#### A. Internal Medicine:

## **B.** Ingredients:

• *Rasam*(*Hydrargyrum*) -17.5gms

• Serangkottai(Semicarpusanacordium) -35gms

#### **Purification of Raw Drugs:**

#### Serangkottai (Semecarpus anacardium)

After removing the knob of serangkottai, it should be soaked in rice washed water and buffalo milk for 3 hours each respectively, and they weregently washed with water and dried in sunlight.

#### **Action:**

Aninflamatory

## Rasam (Hydrargyrum)

Mercury is grinded with brick powder and turmeric powder 1 hour each respectively. The contents were washed with purified water and then Acalyphaindica extract is added. Then the content was boiled till the extract dries.

#### **Action:**

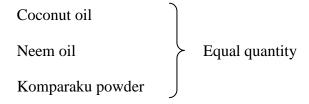
Deobstruent

### **Method of preparation:**

Grind these are drugs grainded in a kalvam for 6 hours, till it changes into wax consistency. And then it was carefully stored ina porcelain container.

#### **B. External Medicine:**

#### **Ingredients:**



#### **Purification of drug:**

#### **Coconut oil (Cocos nucifera):**

Coconut oil and coconut milk are mixed in an equal amount and they were boiled.

#### **Action:**

Anti -inflammatory

#### Neem oil (Azadirachta indica):

Equalamount of neem oil and neem bark decoction was added, boiled and then filtered.

#### **Action:**

Anti -inflammatory

## Komparakku (Carteria lacca):

After cutting, the stick present inside were removed.

#### **Action:**

Anti –arthritic

Anti –inflammatory

## **Method of preparation:**

Equal quantity of all the ingredients are mixed and heated. When the mixture attainedsoil consistency, the oil was allowed to cool and bottled up.

## **Drug storage:**

The trial drug *Vithu Rasa Mezhuugu* was stored in clean and dry container and *MurivuEnnai*was stored in clean and dry bottles.

## **Dispensing:**

The Mezhuguwas given in packets and Ennais given in dry container.

#### VARMAM POINTS APPLIED TO THE PATIENTS:

- Mootupathaipuvarmam
- Sirattaivarmam
- Kaalmootuvarmam
- Mozhiporuthuvarmam

**MOOTU PATHAIPU VARMAM:** 

**Location:** 

This varmam present 6 fingers adjacent to mootu sirattai varmam, in both sides of

the legs.

**SIRATTAI VARMAM:** 

Location:

This varmam present in the pattela bone and also, areas around the patella bone.

This varmam present two fingers above the naaithalai varmam.

**KAAL MOOTU VARMAM:** 

Location:

This varmam present above the mid point of sirattaivarmam in the anterior aspect

of knee joint. Three fingers adjacent to this varmam, asaguthiri kannu varmam is located.

Sometimes the area between asaguthirikannuvarmam can also be taken as

mootuvarmam.

**MOZHIPORUTHU VARMAM:** 

**Location:** 

This varmam is present at the back of knee joint. It is present nine fingers

adjacent to the backsides of mootusirattaivarmam.

SUBJECT SELECTION:

Patients reported with the symptoms of Muzhangal mootu savvu kayangal-knee

joint ligament injury were subjected to screening using their screening Profoma. Then

they were allowed for the study, subjected to the fulfillment of the following criteria.

**INCLUSION CRITERIA:** 

• Age: 20 - 60Yrs

• Sex : Both male and female

• Pain and tenderness, often sudden and severe in the knee joints

• Pain gets worse while walking.

• Swelling present in the knee joint.

• A feeling of looseness in the knee joint.

• Patients willing to undergo radiological investigation and Laboratory

investigations.

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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:**

- Complete ligament tear of the knee joint
- Posterior cruciate ligament tear
- Evidence of bony fractures in X-rays
- H/o Cardiac diseases
- S H/o Diabetes mellitus
- H/o Rheumatoid arthritis
- H/o Chronic kidney disease
- Pregnancy and lactation
- Septic arthritis
- Gonococcal arthritis
- Psoriatic arthritis
- Patient with any other serious systemic illness.

## 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

#### **A.CLINICAL ASSESSMENT:**

- Pain
- Swelling
- Stiffness
- Tenderness
- Restricted movements
- Positive knee joint ligament test

## **KNEE JOINT LIGAMENT EXAMINATION:**

## 1. Anterior drawer sign:

The anterior drawer test examine for any tearing or laxity of the anterior cruciate ligament.

#### 2. Posterior drawer test:

The posterior drawer test is used to examine the posterior cruciate ligament.

## 3. Valgus test:

The valgus stress test checks for medial joint laxity, which usually represents an injury to the medial collateral ligament.

#### 4. Varus test:

The varus stress test checks for joint laxity on the outside of the knee, which usually represents an injury to the lateral collateral ligment.

## 5. McMurray's test:

This test checks for meniscal tears and other internal derangement in the knee.

## **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:**

MRI (Magnetic Resonance Imaging)

## **D. SIDDHA PARAMETERS:**

## **Envagaithervugal:**

Naadi

Sparisam

Naa

Niram

Mozhi

Vizhi

Malam

Moothiram

- NeerkKuri
- Neikkuri

#### **DATA COLLECTION FORMS:**

Required information was 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

#### STUDY ENROLLMENT:

Patients who were reported at the OPD with the clinical symptoms of *Muzhangalmootusavvukayangal* (Ligament injury-knee joint) was examined clinically and then enrolled in the study based on the inclusion and exclusion criteria.

The patients who were enrolled was 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 was obtained from them in writing format, in the consent form (Form VI). All those patients were given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctor's contact details etc. were given, so as to report easily when any complications arises.

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

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

The trial drugs Vithu Rasa Mezhugu (Internal) was given for 9days and MurivuEnnai(External)was given continuously for 48 days for all the 30 patients. Out of those 30 patients, 15 patients are provided with varmam therapy. Patients were requested to visit the hospital OPD once in seven days for this study. Willing cases were admitted in the IPD and progress was assessed daily. In every visit, the clinical assessment was done and prognosis was noted in the prescribed profomas in the presence of Faculty members of Dept. of SirappuMaruthuvam. Laboratory investigations and radiological investigation are done before the administration of the drug and the last day of the trial, laboratory investigation done again for screening. DATA ANALYSIS:

After enrolling the patient for the study, a separate file for each patient was opened and all forms were kept in the file. Study No. and Patient No. was written on the top of file for easy identification. Whenever the patient visited OPD during the study period, their file was taken and necessary entries was made at the assessment form or other suitable form. The screening forms were filed separately. The data recordings was monitored for completion and adverse event by pharmacovigilance committee. And then, All forms were 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 was permitted for unbiased report.

#### **PHARMOCOVIGILANCE**

#### ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT

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

#### **OUTCOME:**

#### **Primary outcome:**

Primary outcome of the study is pain relieving and it will be assessed by the following methods:

#### **KOOS** Scoring instructions

Assign the following scores to the boxes:

None	Mild	Moderate	Severe	Extreme
0	1	2	3	4

Each subscale score is calculated independently. Calculate the mean score of the individual items of each subscale and divide by 4 (the highest possible score for a single answer option). Traditionally in orthopedics, 100 indicates no problems and 0 indicates extreme problems. The normalized score is transformed to meet this standard.

#### WOMAC - How to score from the KOOS

Assign scores from 0 to 4 to the boxes as shown above. To get original WOMAC Scores, sum the item scores for each subscale. If you prefer percentage scores in accordance with the KOOS, use the formula provided below to convert the original WOMAC scores.

Transformed scale = 100	- actual raw score x 100 maximum score	
WOMAC subscores	Original score = sum of the following items	Maximum score
Pain	P5-P9	20
Stiffness	S6-S7	8
Function	A1-A17	68

#### **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 was used.
- 2. No other external or internal medicines were used, other than the trial drug for *Muzhangal mootu savvu kayangal*. There was no infringement on the rights of the patient.
- 3. The data collected from the patient was kept confidential.
- **4.** Only After getting the consent of the patient (through consent form in their own vernacular language), they were enrolled in the study.
- **5.** Treatment was provided free of cost.
- **6.** In any adverse reaction observed during the trial, the patients were withdrawn and given alternative treatment at National Institute of Siddha for further management.

#### **DRUG REVIEW**

## INTERNAL MEDICINE: VITHURASA MEZHUGU

#### **PROPERTIES OF DRUGS:**

## <u>RASAM</u>

English name : Hydrargyram(Mercury quick silver)

Organoleptic character :

Taste : Inippu(sweet), Pulippu(sour), Uppu(salty),

kaippu(bitter),

Kaarpu(pungent), Thuvarpu(astringent).

**Potency** : Veppam and Thatpam

பொதுகுணம்

"விழிநோய் கிரந்திகுன்மம் மெய்ச்சூலைபுண்குட்

டழிகாலில் விந்தவினால் அத்தை-வழியாய்

புரியு விதி யாது புரியினோ யெல்லாம்

இரியுவிதி யாது மில்லை"

### **Action:**

- Deobstruvent
- Anti syphilitic
- Antibilious
- Nutrient
- Alterative
- Sialogogue
- Laxative
- Diuretic

## **SERANKOTTAI**

**Botanical name** : Semecarpusanacordium

**English name** : Marking nut tree, Original cashew

Family : Anacardiaceae

Organoleptic character :

Taste : Kaippu(Bitter), Viruviruppu

**Potency** : Veppam

**Division** : Kaarpu(Pungent)

## பொதுகுணம்

"குட்டம் கயரோகங் கொல்லும் விடபாகந் துட்டந் தருகிருமி சூலையும் போம்-மட்டலருங் கூந்தன்மயி லேகிரந்தின் கூட்டம்போ செங்கையில் ஏந்து சேங் கொட்டைதனை யே

சேங்கொட்டை மெய்த்திமிரைத் தீராக் கடிவிடத்தைப் பாங்கொட்டு மூலத்தைப் பற்றறுக்கும்-ஆங்கெட்டிக் கொல்லும்வா தந்தினோடு குன்மத்தை யும்மதனை வெல்லும் அயிற்கண்ணோய் விள்".

#### **Chemical constituents:**

Anacordic acid, Cardol, Catechol, Anacardol, Fixed oil, Semecarpol, Bhilawanol

#### **Actions:**

- Alterative
- Caustic

#### **EXTERNAL MEDICINE** : MURIVUENNAI

#### **KOMPARAKKU**

English name : Caterialacca (or) Coccuslacca (or)

Tachardialacca

Organoleptic charecters :

**Taste** : Thuvarpu(Astringent), Kaippu(Bitter)

**Potency** : Veppam

**Division** : Kaippu(Bitter)

## பொதுகுணம்

"குட்ட மசிர்க்கு பித்தங் குன்மமிரை பென்புருக்கி பட்டிடு புண்ணாகச்சூர் பங்கநோய் தொட்போ நரகரக்கு சந்திசுர மையமிவைக் கொல்லோ மரகரக்குநூலை யறி"

#### **Actions:**

- Astringents
- Alterative

## **THENGAIENNAI**

**Botanical name** : Cocosnucifera

**English name** : Coconut tree, coconut palm

Family : Aracaceae

Organoleptic character :

Taste : Inippu(Sweet)

**Potency** : Thatpam

**Division** : Inippu(Sweet)

## பொதுகுணம்

"தேங்காயி னெய்யதனாற் றியால்வருபுண்போம் பாங்காகக் கூந்தற் படர்ந்தேறு- நீங்காத பல்லடியின் னோயும் படர்தா மரைசிரங்கும் அல்லறப் போமென் றறி".

#### **Chemical composition:**

Lauric acid, Myristic acid, Caprylic acid, Capric acid, Caproic acid, Palmitic acid, Oleic acid, Palmitoleic acid, Linoleic acid, Linolenic acid, Stearic acid

#### **Actions:**

- Refrigerant
- Aperient
- Nutrient
- Diuretic

## **VEPPENNAI**

**Botanical name** : Azadirachtaindica

**English name** : Margosa tree, Neem tree, Indian lilac

Family : Meliaceae

**Organoleptic character:** 

**Taste** : Kaippu(Bitter)

**Potency** : Veppam

**Division** : Karppu(Pungent)

## பொதுகுணம்

"வாதம்போம் பித்தமிகும் மாறாக்கி ரந்தியொடு மோதுகரப்பான்சிரங்குமுன்னிசிவும்-ஓதுடலின் நாப்ப ணுறுசுரமு நாடுசன்னி யுந்தொலையும் வேப்பநெய் யென்றொருக்கால் விள்ளு"

## **Chemical composition:**

Azadirachtin, Nimbin, Stigmasterol, Campesterol, beta-sitosterol.

#### **Actions:**

- Stimulant
- Antiseptic
- Insecticide

RASAM



SERANKOTTAI



KOMPARAKKU



## MURIYU ENNAI



## VITHU RASA MEZHUGU

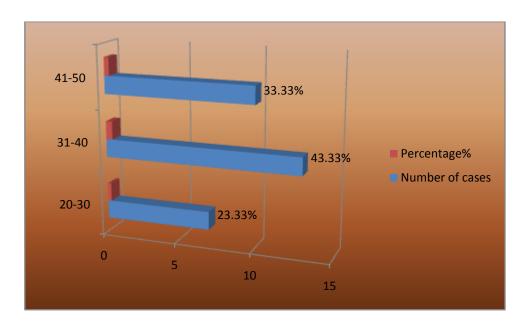


## **OBSERVATION AND RESULTS**

- 1. Age Distribution
- 2. Gender Distribution
- 3. Gunam
- 4. Yakkai illakanam
- 5. Seasonal Distribution
- 6. Land And Disease
- 7. Socio-Economic Status
- 8. Dietary Habits
- 9. Occupational Status
- 10. Duration Of Illness
- 11. Distribution Of Mukkutram
- 12. Ennvagai Thervugal
- 13. Neikuri
- 14. Naadi
- 15. Distribution of Udal Thathukal
- 16. Clinical Features
- 17. Involvement Of Knee Joints
- 18. Precipitating Factors
- 19. Outcome Measurement
- 20. Results After Treatment

## 1. AGE DISTRIBUTION:

S.NO	Age(year)	Number of cases	Percentage%
1.	20-30	7	23.3%
2.	31-40	13	43.3%
3.	41-50	10	33.3%
4.	Total	30	100%

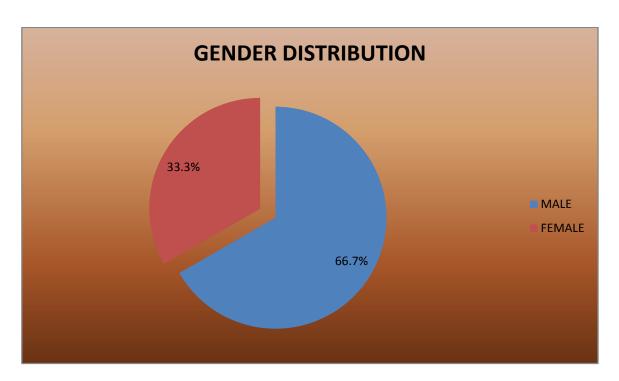


## **Observation:**

The patients were selected from all age groups as given above and the maximum numbers of patients(13) ie. 43.30%, were in the age between 31 and 40.

## 2. GENDER DISTRIBUTION:

S.NO	Gender	Number of cases	Percentage%
1.	Males	20	66.7%
2.	Females	10	33.3%
3.	Total	30	100%

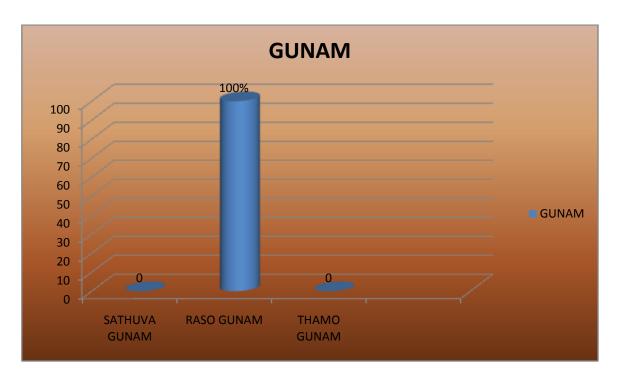


## **Observation:**

Among the 30 patients selected for this study, male were 33.3% and female were 66.7%.

## 3.GUNAM (QUALITY AND CHARACTER)

SI. NO	Gunam	No of cases	Percentage
1	Sathuva gunam	-	-
2	Raso gunam	30	100
3	Thamo gunam	-	-



## **Observation:**

All the patients (100%) had Raso gunam.

## 4. YAAKAI ILAKKANAM (PHYSICAL CONSTITUTION)

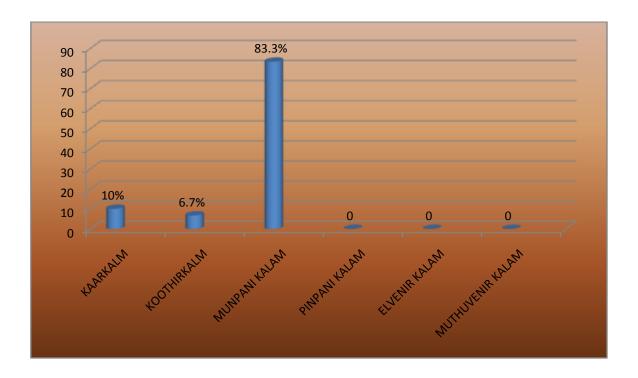
SI. NO	Yaakai ilakkanm	No of cases	Percentage
1	Vatha udal	-	-
2	Pitha udal	-	-
3	Kaba udal	-	-
4	Vaathapitha udal	12	40%
5	Vaathakaba udal	3	10%
6	Pithavaatha udal	10	33.33%
7	Pithakaba udal	5	16.67%

## **Observation:**

Out of 30 cases, 12 patients had *Vaathapitha udal*, 3 patients had *Vaathakaba udal*, 10 patients had *Pithavaatha udal* and 5 patients had *Pithakaba udal* 

## **5. SEASONAL DISTRIBUTION:**

S.No.	Season	Number of cases	Percentage%
1	Kaar kaalam	3	10%
2	Koothir kaalam	2	6.7%
3	Munpani kaalam	25	83.3%
4	Total	30	100%



## **Observation:**

Out of 30 patients, 3 patients reported in *Karkaalam*, 2 patients in *Koothirkaalam* and 25 patients reported in *Munpanikaalam*.

## 6. LAND AND DISEASES:

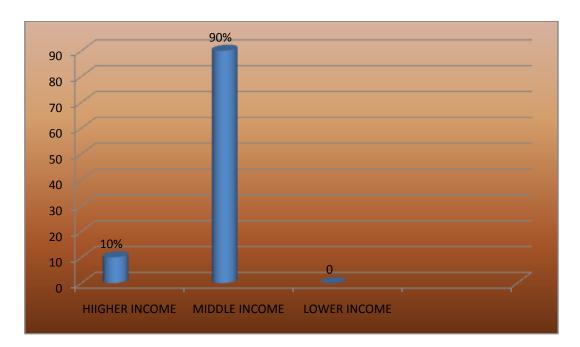
S.No.	Thinai	Number of cases	Percentage%
1	Kurinji	-	-
2	Mullai	3	10%
3	Marutham	9	30%
4	Neithal	18	60%
5	Paalai	-	-
6	Total	30	100%

## **Observation:**

Out of 30 patients, 3 patients were from *Mullai*, 9 patients from *Marutham* and 18 patients from *Neithal*.

## 7. SOCIO- ECONOMIC STATUS:

S.No	Socio- economic status	Number of	Percentage%
		cases	
1	Higher economic status	3	10%
2	Middle economic status	27	90%
3	Lower economic status	1	_
4	Total	30	100%

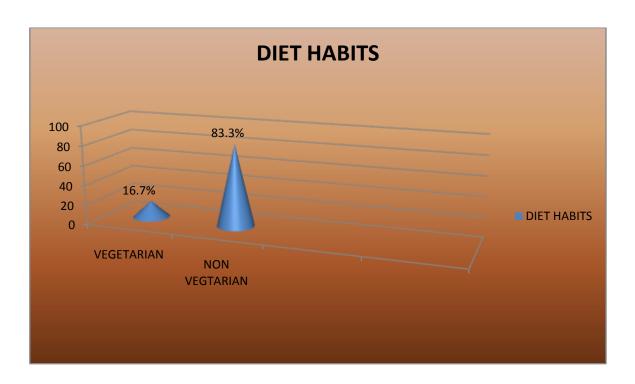


## **Observation:**

Out of 30 cases 10% cases from upper and 90% cases were from middle economic status.

## **8. DIETARY HABITS:**

S.NO	Dietary habits	Number of cases	Percentage%
1	Vegetarian	5	16.7%
2	Non- vegetarian	25	83.3%
3	Total	30	100%

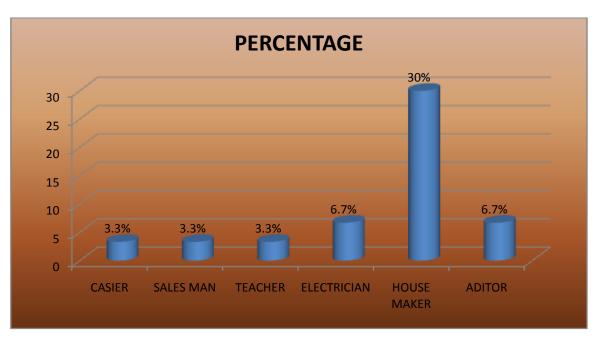


## **Observation:**

Out of 30 cases 83.3% of cases were Non-vegetarians and 16.7% of cases were Vegetarians

## 9. OCCUPATIONAL STATUS:

S.NO	Occupation	Number of cases	Percentage%
1	Casier	1	3.3%
2	Sales man	1	3.3%
3	Teacher	1	3.3%
4	Electrician	2	6.7%
5	Home maker	9	30%
6	Aditior	2	6.7%
7	Airforce offcer	3	10%
8	Student	2	6.7%
9	Supervisor	7	23.3%
10	Lawyer	1	3.3%
11	Staffnurse	1	3.3%
12	Total	30	100%

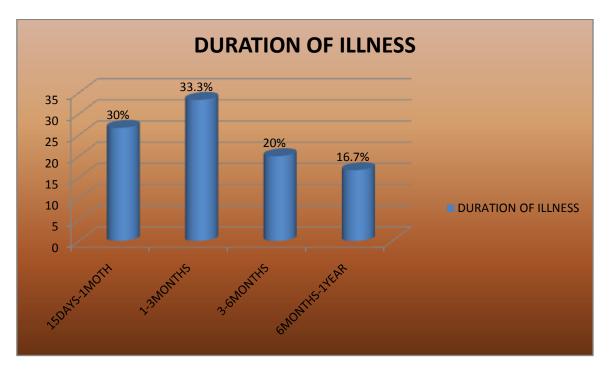


## **Observation:**

The majority of patients (30%) in this study were Home maker.

## 10. DURATION OF ILLNESS:

S.NO	Duration of illness	Number of cases	Percentage%
1	15 days-1month	9	30%
2	1-3 months	10	33.3%
3	3-6 months	6	20%
4	6months-1 year	5	16.7%
5	Total	30	100%



## **Observation:**

Among 30 cases, the duration of illness were 33.3% cases 1 months to 3 months, 30% cases in 15 days to 1 month, 20% cases in 3 months to 6 months, 16.7% cases in 6 months to 1 year.

## 11. DISTRIBUTION OF MUKKUTRAM:

The derangements of Vatham, Pitham and Kabam in MMSK are as follows

## a) Vatham

SI. No	Classification of Vatham	No of cases	Percentage
1	Pranan	-	-
2	Abanan	-	-
3	Uthanan	-	-
4	Samanan	30	100%
5	Viyanan	30	100%
6	Naagan	-	-
7	Koorman	-	-
8	Kirukran	-	-
9	Devathaththan	-	-
10	Dhananjeyan	-	-

## **Observation:**

Out of 30 cases Viyanan and Samanan were affected in all the 30 patients (100%).

## b) Pitham

SI. NO	Classification of <i>Pitham</i>	No of cases	Percentage
1	Anarpitham	-	-
2	Ranajgapitham	-	-
3	Sathagapitam	30	100%
4	Alosagapitham	-	-
5	Pirasagapitham	-	-

## **Observation:**

Out of 30 cases saathagam was affected in almost all the 30 cases (100%)

## c) Kabam

SI. NO	Classification of Pitham	No of cases	Percentage
1	Avalambagam	-	-
2	Kilethagam	-	-
3	Pothagam	-	-
4	Tharpagam	-	-
5	Santhigam	30	100%

## **Observation:**

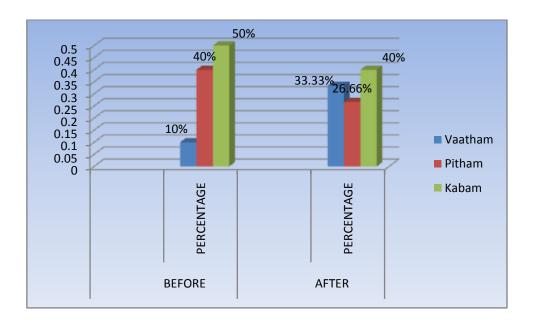
Out of 30 cases Santhigam was affected in almost all the 30 cases (100%).

## 12. ENVAGAI THERVUGAL:

In Siddha system of Medicine, the eight types of investigative procedure were adopted for clinical approach and diagnosis. The investigations were done properly and observations were tabulated.

## Neikkuri:

S.NO	Neikkuri	BEFORE		AFTER	
		NO.OF	PERCENTAGE	NO.OF	PERCENTAGE
		CASES		CASES	
1	Vaatham	3	10%	10	33.33%
2	Pitham	12	40%	8	26.66%
3	Kabam	15	50%	12	40%
4	Total	30	100%	30	100%



## **Observation:**

Out of 30 cases, Before treatment, in 50% of cases Neikkuri was found as Vaatham, 40% of cases found as pitham and 10% cases found as kabam. After treatment, in 33.33% of cases Neikkuri was found as Vaatham, 26.66% of cases found as pitham and 40% cases found as kabam.

### **14. NAADI:**

S.No	Naadi	BEF	ORE	AFTER		
		No. of cases	Percentage%	No.of cases	Percentage%	
1	Vaatha pitham	8	26.7%	20	66.66%	
2	Vaatha kabam	-	-	-		
3	Pitha vaatham	21	70%	6	20%	
4	Pitha kabam	1	3.3%	2	6.66%	
5	Kaba vaatham	-	-	2	6.66%	
6	Kaba pitham	-	-	-	-	
7	Total	30	100%	30	100%	

### **Observation:**

Among 30 cases, Before treatment, vaathapitham naadi was found in 8 patients, 21 were found in Pithavaatham and 1 had pithakabavatham. After treatement, vaathapitham naadi was found in 20 patients, 6 were found in Pithavaatham, 2 had pithakabam and 2 had kabavaatham.

### 15. DISTRIBUTION OF UDAL KATTUKAL

SI. No	Udal kattukal	No of cases	Percentage	
1	Saaram	30	100%	
2	Senneer	-	-	
3	Oon	30	100%	
4	Kozhupu	-	-	
5	Enbu	-	-	
6	Moolai	-	-	
7	Sukkilam/suronitham	-	-	

### **Observation:**

- The Seven thathukkal which constitute our body structure and help to maintain the normal physiological functions.
- Among the 7 Udal Kattugal, Saaram and Oon were affected in all the 30 cases (100%).

### 17. INVOLVEMENT OF KNEE JOINTS:

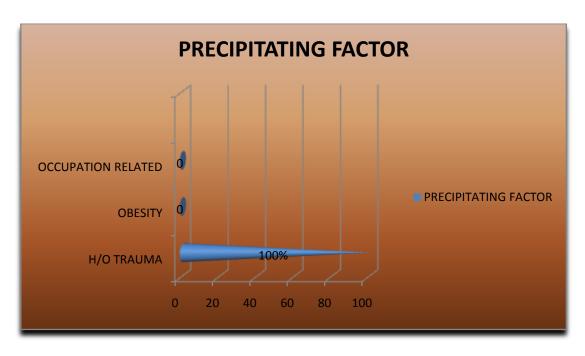
Involvement of knee joints	Number of cases	Percentage%
Both knee joints	0	-
Single knee joint only	30	100%
Total	3	100%

### **Observation:**

Out of 30 cases single knee joints were affected in 30 patients (100%).

### 18. PRECIPITATING FACTOR:

Precipitating factor	Number of cases	Percentage%
H/o trauma	30	100%
Obesity	-	-
Occupation related	-	-
Total	30	100%



### **Observation:**

Out of 30 cases 100% of cases were underwent Trauma.

# RESULTS OF VARMAM MANIPULATION ACCORDING TO KOOS SCORE CLINICAL IMPROVEMENT (SYMPTOMS SCORE)

					SYMPTON	MS SCORE
S.NO	OPD/IPD NO	NAME	AGE	SEX	BEFORE	AFTER
	NO				TREATMENT	TREATMENT
					(%)	(%)
1	K08130	Sakthi valli	26	M	17.86	71.43
2	I15391	Mohan	37	M	21.43	85.71
3	K60982	Kavitha	38	F	25	71.43
4	K96010	Muralikrishnan	40	M	17.86	82.14
5	H02677	Ravichandran	48	M	28.57	82.14
6	L02052	Sivakumar	44	M	17.86	82.14
7	L03153	Sarava kumar	30	M	25	82.14
8	5525	Maheshkumar	20	M	32.14	75
9	F002104	Aruldoss	47	M	21.43	71.43
10	L04732	K.Anand	28	M	21.43	75
11	J18103	Ramani	38	F	25	71.43
12	5556	Rajesh	38	M	25	78.57
13	5565	Gokulnath	22	M	25	78.57
14	K86778	Akshayashree	37	F	10.71	82.4
15	L18268	Mathivanan	37	M	17.86	71.43

### CLINICAL IMPROVEMENT(PAIN SCORE)

					SYMPTON	MS SCORE
S.NO	OPD/IPD	NAME	AGE	SEX	BEFORE	AFTER
	NO				TREATMENT	TREATMENT
					(%)	(%)
1	K08130	Sakthi valli	26	M	16.67	80.56
2	I15391	Mohan	37	M	13.89	75
3	K60982	Kavitha	38	F	19.4	72.22
4	K96010	Muralikrishnan	40	M	16.67	75
5	H02677	Ravichandran	48	M	19.4	83.33
6	L02052	Sivakumar	44	M	19.4	86.11
7	L03153	Sarava kumar	30	M	25	75
8	5525	Maheshkumar	20	M	25	86.11
9	F002104	Aruldoss	47	M	16.67	69.44
10	L04732	K.Anand	28	M	19.44	83.33
11	J18103	Ramani	38	F	13.89	69.44
12	5556	Rajesh	38	M	27.78	83.33
13	5565	Gokulnath	22	M	19.44	80.56
14	K86778	Akshayashree	37	F	22.22	83.33
15	L18268	Mathivanan	37	M	16.67	69.44

## CLINICAL IMPROVEMENT(FUNTION, DAILY LIVING SCORE)

					SYMPTON	MS SCORE
a 110	OPD/IPD	37.43.65		a Ext	BEFORE	AFTER
S.NO	NO	NAME	AGE	SEX	TREATMENT	TREATMENT
					(%)	(%)
1	K08130	Sakthi valli	26	M	20.59	82.35
2	I15391	Mohan	37	M	23.53	72.06
3	K60982	Kavitha	38	F	19.12	73.53
4	K96010	Muralikrishnan	40	M	17.65	76.47
5	H02677	Ravichandran	48	M	20.59	82.35
6	L02052	Sivakumar	44	M	13.24	77.94
7	L03153	Sarava kumar	30	M	22.06	80.88
8	5525	Maheshkumar	20	M	23.53	80.88
9	F002104	Aruldoss	47	M	16.18	70.59
10	L04732	K.Anand	28	M	27.94	80.88
11	J18103	Ramani	38	F	14.71	70.59
12	5556	Rajesh	38	M	23.53	83.82
13	5565	Gokulnath	22	M	19.12	72.06
14	K86778	Akshayashree	37	F	13.24	86.76
15	L18268	Mathivanan	37	M	20.59	73.53

## ${\bf CLINICAL\ IMPROVEMENT(FUNTION, SPORTS\ AND\ RECREATONAL} \\ {\bf ACTIVITES\ SCORE)}$

					SYMPTON	AS SCORE
S.NO	OPD/IPD	NAME	AGE	SEX	BEFORE	AFTER
5.110	NO	IVAIVIL	AGE	SLA	TREATMENT	TREATMENT
					(%)	(%)
1	K08130	Sakthi valli	26	M	10	60
2	I15391	Mohan	37	M	10	65
3	K60982	Kavitha	38	F	10	70
4	K96010	Muralikrishnan	40	M	15	70
5	H02677	Ravichandran	48	M	15	65
6	L02052	Sivakumar	44	M	10	80
7	L03153	Sarava kumar	30	M	15	65
8	5525	Maheshkumar	20	M	15	80
9	F002104	Aruldoss	47	M	15	60
10	L04732	K.Anand	28	M	20	70
11	J18103	Ramani	38	F	20	70
12	5556	Rajesh	38	M	10	75
13	5565	Gokulnath	22	M	20	70
14	K86778	Akshayashree	37	F	10	75
15	L18268	Mathivanan	37	M	20	65

## CLINICAL IMPROVEMENT(QUALITY OF LIFE SCORE)

		NAME		SEX	SYMPTON	SYMPTOMS SCORE	
S.NO	OPD/IPD		AGE		BEFORE	AFTER	
3.110	NO	INAME	AGE	SEA	TREATMENT	TREATMENT	
					(%)	(%)	
1	K08130	Sakthi valli	26	M	31.25	75	
2	I15391	Mohan	37	M	25	81.25	
3	K60982	Kavitha	38	F	12.5	81.25	
4	K96010	Muralikrishnan	40	M	18.75	75	
5	H02677	Ravichandran	48	M	18.75	75	
6	L02052	Sivakumar	44	M	12.5	81.25	
7	L03153	Sarava kumar	30	M	18.75	81.25	
8	5525	Maheshkumar	20	M	25	81.25	
9	F002104	Aruldoss	47	M	18.75	75	
10	L04732	K.Anand	28	M	25	75	
11	J18103	Ramani	38	F	25	68.75	
12	5556	Rajesh	38	M	18.75	81.25	
13	5565	Gokulnath	22	M	18.75	87.5	
14	K86778	Akshayashree	37	F	25	87.5	
15	L18268	Mathivanan	37	M	18.75	75	

## RESULTS OF WITHOUT VARMAM MANIPULATION ACCORDING TO KOOS SCORE

### CLINICAL IMPROVEMENT(SYMPTOMS SCORE)

					SYMPTON	MS SCORE
S.NO	OPD/IPD	NAME	AGE	SEX	BEFORE	AFTER
	NO	·			TREATMENT	TREATMENT
					(%)	(%)
1	K64880	Meenatchi	46	F	32.14	78.57
2	L13330	Bhuvaneshwari	35	F	14.29	82.14
3	K27997	Shakilabanu	40	F	10.71	71.43
4	J63195	A.K.Singh	48	M	14.29	64.29
5	L15438	Chandramohan	35	M	32.14	75
6	K99836	A.Anand	42	M	17.86	85.71
7	L08775	Pandey	29	M	14.29	85.71
8	H47521	Nagaraj	48	M	14.29	71.43
9	L08785	Natarajan	27	M	32.14	78.57
10	L11402	A.Saravanan	44	M	21.43	82.14
11	L03321	Rajesh	33	M	28.57	78.57
12	L13877	Sasikala	46	F	25	78.57
13	J31798	Gokila	34	F	17.86	75
14	L22271	Jayanthi	33	F	14.29	78.57
15	D098267	Kalaiselvi	48	F	14.29	85.7

### CLINICAL IMPROVEMENT(PAIN SCORE)

					SYMPTON	SYMPTOMS SCORE	
S.NO	OPD/IPD	NAME	AGE	SEX	BEFORE	AFTER	
	NO				TREATMENT	TREATMENT	
					(%)	(%)	
1	K64880	Meenatchi	46	F	33.33	80.56	
2	L13330	Bhuvaneshwari	35	F	13.89	86.11	
3	K27997	Shakilabanu	40	F	16.67	72.2	
4	J63195	A.K.Singh	48	M	16.67	63.89	
5	L15438	Chandramohan	35	M	27.78	80.56	
6	K99836	A.Anand	42	M	30.56	75	
7	L08775	Pandey	29	M	30.56	72.22	
8	H47521	Nagaraj	48	M	27.78	77.78	
9	L08785	Natarajan	27	M	33.33	86.11	
10	L11402	A.Saravanan	44	M	22.22	80.56	
11	L03321	Rajesh	33	M	33.33	80.56	
12	L13877	Sasikala	46	F	27.78	80.56	
13	J31798	Gokila	34	F	13.89	77.78	
14	L22271	Jayanthi	33	F	22.22	80.56	
15	D098267	Kalaiselvi	48	F	16.67	83.33	

## CLINICAL IMPROVEMENT(FUNCTION, DAILY LIVING SCORE)

					SYMPTON	MS SCORE
S.NO	OPD/IPD	NAME	AGE	SEX	BEFORE	AFTER
	NO				TREATMENT	TREATMENT
					(%)	(%)
1	K64880	Meenatchi	46	F	32.35	79.41
2	L13330	Bhuvaneshwari	35	F	17.65	80.88
3	K27997	Shakilabanu	40	F	19.12	76.47
4	J63195	A.K.Singh	48	M	16.18	67.65
5	L15438	Chandramohan	35	M	25	82.35
6	K99836	A.Anand	42	M	22.06	83.82
7	L08775	Pandey	29	M	29.41	75
8	H47521	Nagaraj	48	M	22.06	79.41
9	L08785	Natarajan	27	M	32.35	82.35
10	L11402	A.Saravanan	44	M	25	79.4
11	L03321	Rajesh	33	M	23.53	83.82
12	L13877	Sasikala	46	F	27.94	83.82
13	J31798	Gokila	34	F	22.06	83.82
14	L22271	Jayanthi	33	F	22.06	77.94
15	D098267	Kalaiselvi	48	F	22.06	73.53

# ${\bf CLINICAL\ IMPROVEMENT(FUNCTION, SPORTS\ AND\ RECREATIONAL} \\ {\bf ACTIVITIS\ SCORE)}$

					SYMPTON	MS SCORE
					BEFORE	AFTER
S.NO	OPD/IPD				TREATMENT	TREATMENT
	NO	NAME	AGE	SEX	(%)	(%)
1	K64880	Meenatchi	46	F	30	70
2	L13330	Bhuvaneshwari	35	F	15	70
3	K27997	Shakilabanu	40	F	10	65
4	J63195	A.K.Singh	48	M	10	60
5	L15438	Chandramohan	35	M	20	80
6	K99836	A.Anand	42	M	15	70
7	L08775	Pandey	29	M	30	75
8	H47521	Nagaraj	48	M	20	70
9	L08785	Natarajan	27	M	30	80
10	L11402	A.Saravanan	44	M	25	65
11	L03321	Rajesh	33	M	15	65
12	L13877	Sasikala	46	F	30	70
13	J31798	Gokila	34	F	15	70
14	L22271	Jayanthi	33	F	25	75
15	D098267	Kalaiselvi	48	F	15	65

## CLINICAL IMPROVEMENT(QUALITY OF LIFE SCORE)

					SYMPTON	MS SCORE
					BEFORE	AFTER
S.NO	OPD/IPD				TREATMENT	TREATMENT
	NO	NAME	AGE	SEX	(%)	(%)
1	K64880	Meenatchi	46	F	37.50	81.25
2	L13330	Bhuvaneshwari	35	F	12.5	81.25
3	K27997	Shakilabanu	40	F	12.5	68.75
4	J63195	A.K.Singh	48	M	12.5	62.5
5	L15438	Chandramohan	35	M	25	75
6	K99836	A.Anand	42	M	12.5	81.25
7	L08775	Pandey	29	M	31.25	81.25
8	H47521	Nagaraj	48	M	12.5	75
9	L08785	Natarajan	27	M	37.5	75
10	L11402	A.Saravanan	44	M	18.75	81.25
11	L03321	Rajesh	33	M	31.25	81.25
12	L13877	Sasikala	46	F	31.25	75
13	J31798	Gokila	34	F	12.5	68.75
14	L22271	Jayanthi	33	F	31.25	75
15	D098267	Kalaiselvi	48	F	12.5	81.25

### RESULT OF VARMAM MANIPULATION ACCORDING TO KOOS SCORE

					KOOS	SCORE
					BEFORE	AFTER
S.NO	OPD/IPD				TREATMENT	TREATMENT
	NO	NAME	AGE	SEX	(%)	(%)
1	K08130	Sakthi valli	26	M	19	76.8
2	I15391	Mohan	37	M	21.7	75
3	K60982	Kavitha	38	F	12.5	73.2
4	K96010	Muralikrishnan	40	M	17.3	76.2
5	H02677	Ravichandran	48	M	20.8	79.8
6	L02052	Sivakumar	44	M	14.9	81
7	L03153	Sarava kumar	30	M	22.6	78
8	5525	Maheshkumar	20	M	25	81
9	F002104	Aruldoss	47	M	17.7	69.6
10	L04732	K.Anand	28	M	23.8	78.6
11	J18103	Ramani	38	F	17.9	70.2
12	5556	Rajesh	38	M	22.6	81.5
13	5565	Gokulnath	22	M	20.2	76.2
14	K86778	Akshayashree	37	F	15.5	83.9
15	L18268	Mathivanan	37	M	20	73.2

## RESULT OF WITHOUT VARMAM MANIPULATION ACCORDING TO KOOS SCORE

					SYMPTON	MS SCORE
S.NO	OPD/IPD	NAME	AGE	SEX	BEFORE	AFTER
	NO				TREATMENT	TREATMENT
					(%)	(%)
1	K64880	Meenatchi	46	F	32.7	78.6
2	L13330	Bhuvaneshwari	35	F	15.9	81
3	K27997	Shakilabanu	40	F	15.5	72.6
4	J63195	A.K.Singh	48	M	14.9	64.9
5	L15438	Chandramohan	35	M	26.2	79.8
6	K99836	A.Anand	42	M	21.4	80.4
7	L08775	Pandey	29	M	27.4	76.8
8	H47521	Nagaraj	48	M	20.8	76.2
9	L08785	Natarajan	27	M	32.7	81.5
10	L11402	A.Saravanan	44	M	23.2	78.6
11	L03321	Rajesh	33	M	26.2	79.8
12	L13877	Sasikala	46	F	28	79.8
13	J31798	Gokila	34	F	17.9	78
14	L22271	Jayanthi	33	F	22	78
15	D098267	Kalaiselvi	48	F	17.9	77.4

#### 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  $\pm$  Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

#### ACCORDING TO KOOS SCORE

#### BEFORE AND AFTER TREATMENT

Symptom score	Sample size	Mean±SD	95% confidence interval	Significant
Before treatment	30	21.14±4.983	19.6 to 22.7	p < 0.0001
After treatment	30	77.25±4.039	76 to 78.5	p .0.0001

The mean $\pm$  standard deviation of pain score at before and after treatment were 21.14 $\pm$ 4.983 and 77.25 $\pm$ 4.039 respectively which is statistically considered extremely significant (p <0.0001).

## KOOS SCORE ASSESSMENT BEFORE AND AFTER TREATMENT BETWEEN TWO GROUPS:

	Sample	Mear	n±SD	't' v	alue	'p' value		
	size	BT	AT	BT	AT	BT	AT	
With varmam	15	19.433±3.388	76.946±4.053	1.993	0.4175	0.0561	0.6795	
Without varmam	15	22.84±5.688	77.56±4.0029	21,550	011270	0.0001	0.0726	

There is no significant difference between with and without varmam treatment group.

## HB AND RBC – INVESTIGATIONS BEFORE AND AFTER TREATMENT – PATIENTS

SL	OP/IPNO	NAME	Hb g	gm%		RBC n/cumm
NO			B.T	A.T	B.T	A.T
1	K08130	Sakthi valli	12	12.1	4.2	4.2
2	I15391	Mohan	14.6	15	4.9	4.8
3	K60982	Kavitha	16	16.1	5.4	5.3
4	K96010	Muralikrishnan	13.6	13.6	4.4	4.2
5	H02677	Ravichandran	11.3	11.3	4.3	4.4
6	L02052	Sivakumar	11.5	12.2	4	4.1
7	L03153	Sarava kumar	12.1	13.2	4.4	5.4
8	5525	Maheshkumar	12.8	13.1	4.7	4.9
9	F002104	Aruldoss	14.4	14.3	5.3	5.2
10	L04732	K.Anand	15.3	16.1	5	4.5
11	J18103	Ramani	11	12.3	4.7	4.1
12	5556	Rajesh	14	14.2	4.4	4.6
13	5565	Gokulnath	12.3	13.1	4.3	4.7
14	K86778	Akshayashree	13.6	13.7	4.5	4.3
15	L18268	Mathivanan	13.2	13.5	5.1	5
16	K64880	Meenatchi	12.4	13.1	4.3	4.4
17	L13330	Bhuvaneshwari	13.1	14.2	4.7	4.5
18	K27997	Shakilabanu	13.2	13.5	4.9	4.8
19	J63195	A.K.Singh	12.6	13.2	4.6	4.8
20	L15438	Chandramohan	12.1	13.7	5.06	4.9

## HB AND RBC – INVESTIGATIONS BEFORE AND AFTER TREATMENT – OPD PATIENTS

SL.No	OP/IP	NAME	Hb gr	m%	TR Million	
	NO		B.T	A.T	B.T	A.T
21	K99836	A.Anand	13.2	13.5	4.9	4.5
22	L08775	Pandey	13	13.4	4.5	4.7
23	H47521	Nagaraj	13.1	13.4	4.6	4.4
24	L08785	Natarajan	11.7	12.3	4.2	4.2
25	L11402	A.Saravanan	12.3	13.4	4.7	4.9
26	L03321	Rajesh	12.7	13.3	4.2	4.4
27	L13877	Sasikala	15.5	15.8	6.6	6.8
28	J31798	Gokila	10.3	11.1	4.7	4.6
29	L22271	Jayanthi	14.6	15.3	5.1	5
30	D098267	Kalaiselvi	13.3	13.6	4.9	4.6

### BLOOD INVESTIGATIONS BEFORE AND AFTER TREATMENT- PATIENTS

		T	CC C			D	C (%	)					E	SR	
		(mil	lion/	ľ	N			E		Mxd		1/2 HR		1 HR	
S. No	IP/OP NO	cu.ı	mm)												
		BT	AT	BT	A	BT	A	В	A	В	A	В	A	В	A
					T		T	T	T	T	T	T	T	T	T
1	K08130	5100	5200	57	61	34	33	-	-	9	6	18	6	32	12
2	I15391	6900	6800	69	72	26	24	-	-	5	4	2	3	8	6
3	K60982	6300	6400	60	66	35	32	-	-	5	2	2	4	6	8
4	K96010	4200	4400	40	56	53	39	-	-	7	5	2	2	4	4
5	H02677	9600	9800	63	67	33	31	-	-	4	2	22	24	50	52
6	L02052	7200	7600	58	62	36	34	-	-	6	4	4	8	16	12
7	L03153	5300	5600	56	63	39	31	-	-	5	6	20	6	44	12
8	5525	4800	5600	71	73	25	22	-	-	4	5	24	10	50	20
9	F002104	7200	7200	53	55	42	39	-	-	5	6	6	3	12	6
10	L04732	5600	5400	57	63	36	31	-	-	7	6	6	4	12	8
11	J18103	6400	6100	70	72	25	25	-	-	5	3	22	10	46	14
12	5556	5700	6200	60	65	36	29	-	-	4	6	7	20	10	40
13	5565	5600	5900	55	63	37	31	-	-	8	6	6	3	12	6
14	K86778	5600	5800	49	50	42	45	-	-	9	5	22	12	44	24
15	L18268	9600	7500	67	65	31	30	-	-	2	5	2	2	6	4
16	K64880	5400	5200	55	53	38	38	-	-	7	9	10	5	20	10
17	L13330	7700	7500	59	63	30	28	-	-	11	9	32	12	68	24
18	K27997	7500	7800	53	56	38	37	-	-	9	7	2	2	4	4
19	J63195	7100	7200	53	63	40	32	-	-	7	5	6	3	12	6
20	L15438	7200	8800	65	67	30	25	-	-	5	8	4	2	18	8

### BLOOD INVESTIGATIONS BEFORE AND AFTER TREATMENT- PATIENTS

		To				DC	C (%)					ESR	
S.No	IP/OP	(million/ cu.mm)		ľ	N		L		Mxd		1/2 HR		HR
5.110	NO	BT	AT	BT	A	BT	AT	В	A	BT	A	В	AT
					T			T	T		T	T	
21	K99836	7600	7400	58	59	38	36	4	5	2	2	6	6
22	L08775	7000	7000	56	58	39	36	5	6	6	4	12	8
23	H47521	5900	5400	74	62	50	34	3	4	8	6	16	12
24	L08785	7900	7200	68	64	28	28	4	8	8	6	16	12
25	L11402	9700	8600	55	58	41	0	4	3	22	8	58	18
26	L03321	5300	5700	53	56	40	38	7	6	2	2	4	4
27	L13877	8600	7700	52	53	41	40	6	7	2	2	4	4
28	J31798	6700	7600	66	63	29	31	5	6	12	4	24	8
29	L22271	5000	5700	60	63	32	29	8	8	2	2	6	6
30	D098267	7600	8200	63	64	35	32	2	3	4	2	14	10

## SERUM BILIRUBIN & GLUCOSE PROFILE BEFORE AND AFTER TREATMENT - PATIENTS

	VD (OD		Seru	m bilir	ubin (m	g/dl)				COSE FILE	
S.No	IP/OP NO	Dir	rect	Indi	irect	To	tal	FA	ST	P.P.	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	K08130	0.6	0.7	0.2	0.3	0.4	0.4	90	90	108	110
2	I15391	0.7	0.7	0.2	0.2	0.5	0.5	88	92	121	118
3	K60982	0.9	0.9	0.3	0.2	0.6	0.7	95	93	114	110
4	K96010	0.9	1	0.3	0.4	0.6	0.6	91	98	112	118
5	H02677	0.4	0.4	0.2	0.2	0.2	0.2	92	86	108	107
6	L02052	0.6	0.6	0.4	0.3	0.2	0.3	103	96	123	110
7	L03153	1.1	1	0.4	0.3	0.7	0.7	85	86	109	110
8	5525	0.8	0.7	0.2	0.3	0.6	0.4	91	86	122	108
9	F002104	0.6	0.6	0.2	0.3	0.4	0.3	81	91	121	112
10	L04732	0.5	0.4	0.2	0.2	0.3	0.2	94	86	133	122
11	J18103	0.5	0.6	0.2	0.3	0.3	0.3	78	84	118	110
12	5556	0.5	0	0.2	0	0.4	0	96	0	120	0
13	5565	0.6	0.7	0.2	0.1	0.4	0.5	81	18	104	106
14	K86778	0.6	0.7	0.2	0.2	0.4	0.4	89	91	106	112
15	L18268	0.7	0.7	0.2	0.2	0.5	0.4	82	83	101	111
16	K64880	0.9	0.8	0.3	0.2	0.6	0.6	73	78	108	110
17	L13330	0.8	0.7	0.2	0.2	0.6	0.5	76	78	112	110
18	K27997	0.5	0.5	0.2	0.1	0.3	0.3	82	81	104	103
19	J63195	0.8	0.8	0.2	0.1	0.6	0.4	95	97	108	110
20	L15438	0.8	0.7	0.3	0.2	0.5	0.4	92	90	126	118

## SERUM BILIRUBIN & GLUCOSE PROFILE BEFORE AND AFTER TREATMENT - PATIENTS

	IP/OP		Seru	m bilir	ubin (m	ng/dl)			GLUCOSE PROFILE				
S.No	NO	Dir	ect	Indirect		Total		FAST		P.P.			
	1,0	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT		
21	K99836	0.6	0.7	0.2	0.3	0.4	0.4	90	90	108	110		
22	L08775	0.7	0.7	0.2	0.2	0.5	0.5	88	92	121	118		
23	H47521	0.9	0.9	0.3	0.2	0.6	0.7	95	93	114	110		
24	L08785	0.9	1	0.3	0.4	0.6	0.6	91	98	112	118		
25	L11402	0.4	0.4	0.2	0.2	0.2	0.2	92	86	108	107		
26	L03321	0.6	0.6	0.4	0.3	0.2	0.3	103	96	123	110		
27	L13877	1.1	1	0.4	0.3	0.7	0.7	85	86	109	110		
28	J31798	0.8	0.7	0.2	0.3	0.6	0.4	91	86	122	108		
29	L22271	0.6	0.6	0.2	0.3	0.4	0.3	81	91	121	112		
30	D098267	0.5	0.4	0.2	0.2	0.3	0.2	94	86	133	122		

### LIVER FUNCTION TESTS BEFORE AND AFTER TREATMENT - PATIENTS

S.No	IP/OP NO		OT (/dl)		PT (/dl)		pho /dl)		imin (dl)		oulin (dl)	Pro (g/	tein
	110	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	K08130	18	17	14	15	74	77	4.4	4.3	2	2.1	6.4	6.3
2	I15391	21	20	19	20	93	95	4.9	4.1	2.6	2.5	7.5	7.3
3	K60982	26	27	29	28	101	89	4.3	4.2	2.9	2.8	7.1	7
4	K96010	25	80	30	23	74	96	4	3.5	2.8	3	6.8	6.5
5	H02677	15	16	10	10	92	93	5	4.9	2.4	2.6	7.4	7.5
6	L02052	16	18	9	12	83	87	4.6	4.6	2.7	2.7	7.6	7.6
7	L03153	18	19	12	17	96	102	4.6	4.3	2.9	2.4	7.5	6.7
8	5525	13	18	17	15	94	96	3.5	3.6	2.5	2.6	6	6.2
9	F002104	19	0	21	0	106	0	4.3	0	2.3	0	6.6	0
10	L04732	19	18	20	19	100	87	4	3.5	3	3	7	6.5
11	J18103	15	18	8	16	80	93	4.1	4	2.5	2.4	6.6	6.4
12	5556	15	18	8	16	86	93	4.1	4	2.5	2.4	6.6	6.4
13	5565	22	24	28	26	110	97	4.1	4	2.1	2.1	6.2	6.1
14	K86778	23	24	26	25	119	110	3.9	3.8	2.4	2.4	6.3	6.2
15	L18268	36	33	37	31	98	87	4	4	2.1	2	6.1	6
16	K64880	19	20	27	25	107	110	3.3	3.1	3	3	6.3	6.1
17	L13330	17	22	14	18	79	86	5.0	4.5	2.1	2.3	7.1	6.8
18	K27997	19	20	15	18	83	87	4.6	4.2	2.2	2.4	6.8	6.6
19	J63195	18	19	16	14	86	97	4.3	4	3	3.1	7.3	7.1
20	L15438	18	17	15	16	97	110	4.1	4	3.1	3.1	7.2	7.1

### LIVER FUNCTION TESTS BEFORE AND AFTER TREATMENT – PATIENTS

S.No	IP/OP NO		OT (/dl)		PT (/dl)	_	pho /dl)		ı <b>min</b> (dl)		oulin (dl)		T. tein (dl)
	1,0	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	K99836	18	19	19	22	83	93	3.1	3.1	3.5	3.3	6.6	6.4
22	L08775	14	20	16	18	19	110	4.1	4	2.5	2.4	6.6	6.4
23	H47521	22	24	26	24	72	110	3.9	3.6	2.7	2.8	6.6	6.4
24	L08785	14	19	10	14	79	107	4.6	4.4	2.9	2.8	7.4	7.2
25	L11402	14	15	11	12	74	86	4.1	4.2	2.4	2.3	6.5	6.5
26	L03321	18	18	14	14	99	96	4	4.1	2.1	2	6.1	6.1
27	L13877	17	16	14	13	89	80	4.9	4.8	2.3	2.3	7.2	7.1
28	J31798	19	18	24	24	87	96	4.1	4.1	3.4	3.2	7.5	7.3
29	L22271	22	28	25	2.3	88	93	4.2	4.2	2.8	2.6	7	6.8
30	D098267	16	15	19	18	91	96	4.2	4.1	2.8	2.7	7	6.8

## URINE AND MOTIONS EXAMINATION BEFORE AND AFTER TREATMENT PATIENTS

	URINE									
S.	ID /OD	Before Treatment				After Treatment				
NO	NO NO		De			Albumin	Sugar	Dep	osits	
		Albumin	Sugar Pus Epi. Cells cells				Pus Cells	Epi. Cells		
1	K08130	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
2	I15391	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
3	K60982	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
4	K96010	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
5	H02677	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
6	L02052	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
7	L03153	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
8	5525	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
9	F002104	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
10	L04732	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
11	J18103	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
12	5556	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
13	5565	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
14	K86778	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
15	L18268	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
16	K64880	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
17	L13330	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
18	K27997	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
19	J63195	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	
20	L15438	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	

## URINE AND MOTIONS EXAMINATION BEFORE AND AFTER TREATMENT -PATIENTS

		URINE									
a No	IP/OP	Bef	ore Trea	tment		After Treatment					
S.NO	NO	Albumin	Albumin Sugar		bumin Sugar Deposits		Albumin	Sugar	Dep	osits	
				Pus Cells	Epi. cells			Pus Cells	Epi. Cells		
21	K99836	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
22	L08775	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
23	H47521	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
24	L08785	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
25	L11402	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
26	L03321	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
27	L13877	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
28	J31798	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
29	L22271	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		
30	D098267	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL		

#### DISCUSSION

The main aim of the treatment was to study the safety and therapeutic Efficacy of the drug *Vithu rasa mezhugu* and *Murivu ennai* reduce pain, swelling, restriction of movements and other clinical symptoms in the disesae *Muzhangal mootu savvu kayangal*.

The clinical features of *Muzhangal mootu savvu kayangal* can be correlated with Knee joint-Ligament injury in modern science. Ligament injury-knee joint is an annoying and painful condition that limits the functions of the joints. There is a pain and tenderness in the knee joints during standing and walking. The four major ligaments in the knee, the anterior cruciate ligament and the medial collateral ligament are most often injured in sports.

The drugs which possess anti-Vaatha property as mentioned in Siddha literature were selected and the trial drugs were prepared in the Gunapadam practical laboratory of National Institute of Siddha, after getting proper authentication of raw drugs from the Medicinal botany department at NIS, Chennai 47, and Chemistry department in Siddha central Research Institute Arumbakkam Chennai 106, under the supervision of the members of the faculty members. The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

The Biochemical qualitative and quantitative analysis were done at the Biochemistry lab of NIS. It revealed the presence of effective minerals.

The clinical study was conducted with a 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, 30 cases were selected for induction to the trial. Before enrollment into the trial the informed consent was obtained from the patients.

The patients were treated with trial drugs *Vithu rasa mezhugu* (internal) twice a day with Palm jiggery for 9 days and *MurivuEnnai* (external) for 48 days. Patients were instructed to take the medicines regularly advised to follow pathiyam (avoid tamarind, tubers, etc) and advised to avoid cold exposure.

After the treatment, the patients were advised to visit the Out-Patient ward of Department of Sirappu Maruthuvam for another 2 months for follow-up.

#### **OBSERVATIONS:**

The majority affected sex is male (66.7%). The common cause for this is obesity, exposure to athletic activity and motor vehicular accidents. History taking these reveals the above reasons for male predominance.

- This study shows that the highest incidence of *Muzhangal mootu savvu kayangal* is between 31-40 years of age.
- In this study, 60% of cases were reported from Neithal land. In Siddha literatures, it was mentioned that Neithal, which is responsible for Vaatha diseases. This study also emphasized the same.
- Among 30 patients, 25(83.3%) were non-vegetarians and 5 (16.7%) were vegetarians.
- Munpani kaalam showed the highest incidence of 83.3% and 10% were reported during Kaar kaalam and 6.7% were reported during koothir kaalam.
- Viyanan, Samanan were affected in all 30 cases.
- In all the cases the Sathaga pitham was affected.
- Santhigam was affected in all the 30 cases. Santhiga kabam mainly lives in joints and so it was affected in all the cases.
- Pulse reading(Naadi) was observed in all patients. Among 30 cases, Before treatment, vaathapitham naadi was found in 8 patients, 21 were found in Pithavaatham and 1 had pithakabavatham. After treatement, vaathapitham naadi was found in 20 patients, 6 were found in Pithavaatham, 2 had pithakabam and 2 had kabavaatham.
- Out of 30 cases, Before treatment, in 50% of cases Neikkuri was found as Vaatham, 40% of cases found as pitham and 10% cases found as kabam. After treatment, in 33.33% of cases Neikkuri was found as Vaatham, 26.66% of cases found as pitham and 40% cases found as kabam.
- Saaram and Oon were affected in all the 30 cases (100%), and there were no changes noted in other thathukkal like Enbu, Kozhupu, Moolai, Sukkilam and Suronitham.
- Kaal was affected in all the 30 cases (100%).

#### LABORATORY INVESTIGATIONS:

- By laboratory investigation ESR was found raised in 7 patients in early stages but after treatment it was found reduced.
- Blood Urea and Serum Creatinine levels showed no changes in this study.
- The MRI studies showed sprain and partial tear of knee joint ligaments. The trial drug showed improvement in prognosis of the disease clinically rather than in radiographic changes.

#### THERAPEUTIC EFFICACY OF VITHU RASA MEZHUGU:

According to Koos score, The mean symptom assessment before treatment patients who treatedwithout varmam was 22.84 and after treatment it was increased to 77.56.

## THERAPEUTIC EFFICACY OF *VITHU RASA MEZHUGU* ALONG WITH VARMAM:

15 patients are treated with Varmam along with the trial drug. The remaining 15patients received only trial medicines. The results are compared at the end of the study. In this clinical trial, patients who treated with Varmam showed same result as it is in Without varmam patients.

The mean symptom assessment before treatment patients who treated with varmam was 19.433 and after treatment it was increased to 76.946.

#### **EVALUATION OF MEDICINES:**

• The Biochemical study revealed the presence of several minerals. The test drug answered for the presence of Phosphate, Ammonia, Ferrous iron, Tannic Acid, Alkaloids, Calcium, Mercury, Arsenic and Ammonium.

#### **SUMMARY**

The clinical study on *Muzhangal mootu savvu kayangal* 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 study is conducted after approved by the Institutional Ethical Committee (IEC) and the trial was registered in Clinical trial registry of India (REF/2018/09/021429). Hence the study is safely executed on patients and there was no adverse drug reactions noted during the study period.

30 cases of both the sexes (majority of males) with the signs and symptoms of *Muzhangal mootu savvu kayangal* were selected in the age group within 20 to 60 for the study. 15 were given Varmam therapy along with the trial drugs and for the remaining 15 were given only the trial drugs for 48 days. Varmam therapy was given 3 alternative days in a week

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.

From the second day onwards, the patients were treated with the trial drugs *Vithu* rasa mezhugu 65mg bid with palm jaggery was given internally and Murivuennai externally. Every 8<sup>th</sup> day; the patients were assessed for clinical improvement and adverse effects.

Before treatment and at the end of the treatment (49<sup>th</sup> day) the laboratory investigations were done. The MRI of the affected Joints was 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 excretorysystems.

15 patients are treated with varmam along with their trial medicine. The remaining 15 received only trail drugs. The results are compared at the end of the study.

The mean Koos score assessment before treatment was 19.433 and after treatment it was increased 76.946.

The study result was done in all the 30 patients participated in the trial using the Koos score.

#### CONCLUSION

Varmam treatment along with the trial drugs showed same improvement as compared to the patients who were treated only with trial drug. Hence the study reveals the effectiveness of Trial drug intreating Muzhangal mootu savvu kayangal.

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 human beings.

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

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

## PRELIMINARY QUALITATIVE ANALYSIS OF DRUG – VITHU RASA MEZHUGU

### **Preparation of Extract:**

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

SNo	Procedure	Observation	Inference
1.	Test for Calcium:		
	2 ml of extract is taken in a	Cloudy appearance	Presence of calcium
	clean test tube. To this add	and white precipitate	
	2 ml of 4% ammonium	is formed	
	oxide solution.		
2.	Test for Sulphate:		
	2 ml of the extract is added	No white precipitate	Absence of Sulphate
	to 5 % barium chloride	is	
	solution.	Formed	
3.	Test for Chloride :	No cloudy	Absence of Chloride
	The extract is treated with	appearance present	
	Silver nitrate solution		
4.	Test for carbonate :		
	The substance is treated	No effervescence is	Absence of carbonate
	with Conc. HCl.	formed	
5.	Test for Starch :		
	The extract is added with	No blue color is	Absence of starch
	weak iodine solution	formed	
6.	Test for Iron (Ferric) :		
	The extract is treated with	No blue color is	Absence of Ferric
	glacial acetic acid and	formed	iron
	potassium ferrocyanide		

7.	Test for Iron (Ferrous) :	Blood red colour is	Presence of Ferrous iron
	The extract is treated with	formed	
	Conc. HNO3 and		
	ammonium thiocynate		
8.	Test for phosphate :	No Yellow precipitate is	Absence of phosphate
	The extract is treated with	formed	
	ammonium molybdate and		
	conc. HNO3		
9.	Test for Tannic acid: The	No Black precipitate is	Absence of Tannic acid
	extract is treated with Ferric	formed	
	chloride		
10.	Test for Aluminium:	No characteristic	Absence of aluminium.
	To the 2m of the extract	changes.	
	sodium hydroxide is added		
	in drops to excess.		
11.	Test for Lead:	No yellow precipitate is	Absence of lead.
	2ml of the extract is added	obtained.	
	with 2ml of potassium		
	iodide solution.		
12.	Test for alkaloids:	No red colour devloped	
	a. 2ml of the extract is		-
	treated wth 2,1 of potassium		
	Iodide olution.		
	b. 2ml of extract is treated	Yellow colour	Presence of Alkaloid
	with 2 ml of picrid acid.	developed	
	c. 2ml of the extract is treated with 2ml of phosphotungstic acid.	No white precipitate is developed.	-

13.	Test for Mercury:	Yellow precipitate is	
	2ml of the extract is treated	obtained.	Presence of mercury.
	with 2ml of sodium		
	hydroxide solution.		
14.	Test for Arsenic:	Brownish red	Presence of arsenic.
	2ml of the extract is treated	precipitate is obtained.	
	2ml of sodium hydroxide		
	solution.		
15.	Test for Ammonium:	Brown colour	Presence of
	2ml of extract few ml of	appeared.	ammonium.
	Nessler's reagent and		
	excess of sodium hydroxide		
	solution are added.		
16.	Test for Magnesium:	White precipitate is	Presence of
	2ml of extract sodium	obtained.	Magnesium.
	hydroxide solution is added		
	in drops to excess.		

### NATIONAL INSTITUTE OF SIDDHA

राष्ट्रीय सिद्ध संसथान -Ministry of AYUSH - आयुष गंत्रालय GOVERNMENT OF INDIA-भारत सरकार

TAMBARAM SANATORIUM, CHENNAI -600 047 -ताज्वरम सनदोरियम चेन्नई -600 047 फ्रांच\Tele : 044-22411611 केंग्रा\Fax : 22381314

धेतः nischennaisiddha@yahoo.co.in

वेव:www.nischennai.org

F.No.NIS/6-20/Res/IEC/17-18

Date: 28-12-2017

### **CERTIFICATE**

	Institute of Siddha, Tambaram Sanatorium, -600047, Tamil Nadu, India
Principal Investigator: Dr.M.Monika, N Department of S	M.D(S) – II year, Sirappu Maruthuvam - Dissertation –
	rial of Siddha drugs Vithu Rasa Mezhugu Ily in the treatment of Muzhangal Mootu vith and without Varmam therapy.
Documents filed	Protocol, 2) Data Collection forms 3)     Patient Information Sheet 4) Consent form     SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	Yes
Informed consent documents	Yes
Any other documents	780
Date of IEC approval & its number	NIS/13-IEC/2017-1-06/22-11-2017

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 MINISTRY OF AYUSH GOVERNMENT OF INDIA

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www.nischennai.org

F.No:NIS/Gunapadam/Au/2019/22

29.03.2018

### **AUTHENTIFICATION CERTIFICATE**

Certified that the samples submitted for identification by Dr.M.Monika, II year PG scholar, Dept. of Sirappu Maruthuvam, National Institute of Siddha, Chennai - 47, are identified as Rasam-Mercury, Kombharakku-Carteria Lacca on the basis of macroscopic character.

This certificate is issued for the purpose of preparing her dissertation medicine in Gunapadam laboratory, NIS.

Dr. S. Visweswaran, M.D (s)
Head of Department
Department of Gunapadam
National Institute of Siddha
Tembaram Sanatorium, Chennal-47.

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

#### BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation "Vithu Rasa Mezhugu" (Internal) and "Murivennai" (External) taken up for Post Graduation Dissertation studies by Dr.M.Monika M.D.(8). If year, Department of Sirappu Maruthuyam, 2018, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Semecarpus anucardiam I mn. l'(Anacardiaceae). Nut Coeus nucifera L'inn. (Arecaceae). Kernel oil Azadirachta indica A. Juss. (Meliaceae). Seed oil

cate No. MSMB3412018

w Institutio: 02-07-2018

Authorized Signatory

Dr. D. ARAVIND, M.D.(s),M.Sc., Assistant Professor Department of Medicinal Botany National Institute of Siddha



#### 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

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Dr	$\  \cdot \ $		4	V.	A	N	11/	/ D
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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.

all wim

Dr. G.J. Christian

Coordinator
HoD, Dept. of Noi Naadal,
National Institute of Skidha

Prof.Dr.V.Banumath
Director.
National Institute of Siddha
Chennal - 600 047.

#### Clinical Trial Details (PDF Generation Date :- Wed, 17 Jul 2019 18:51:56 GMT)

CTRI Number	CTRI/2018/09/015837 [Registered on: 26/09/2018] - Trial Registered Prospectively							
Last Modified On	25/09/2018							
Post Graduate Thesis	Yes							
Type of Trial	Interventional							
Type of Study	Drug Siddha Other (Specify) [Varm	Drug						
Study Design	Other							
Public Title of Study	Treatment for Knee jo	int ligament injury through Siddha system of medicine.						
Scientific Title of Study		rial of Siddha drugs Vithu Rasa Mezhugu internally and Murivu Ennai nent of Muzhangal Mootu Savvu Kayangal (Ligament Injury)with and without						
Secondary IDs if Any	Secondary ID	Identifier						
	NIL	NIL						
Details of Principal	1	Details of Principal Investigator						
Investigator or overall	Name	Dr Monika M						
Trial Coordinator	Designation	Pg scholar						
(multi-center study)	Affiliation	National Institute of Siddha.						
	Address	National Institute of Siddha, Tambaram sanatorium, Chennai-47,						
		Tamil Nadu. Raja silks, Uranipuram(po), Orathanadu(tk), Tanjavur(dt) 614614 Chennai TAMIL NADU 600047 India						
	Phone	8056367363						
	Fax							
	Email	text2moni@gmail.com						
Details Contact	T. Control of the Con	Details Contact Person (Scientific Query)						
Person (Scientific	Name	Dr V Mahalakshmi MDs						
Query)	10000000							
	Designation	Lecturer  National Institute of Siddha						
	Affiliation	National Institute of Siddha						
Address		National Institute of Siddha, Tambaram sanatorium, Chennai-47, Tamil Nadu Chennai TAMIL NADU 600047 India						
	Phone	9444519975						
	Fax							
	Email	rvmahalakshmi85@gmail.com						
Details Contact		Details Contact Person (Public Query)						
Person (Public Query)	Name	Dr V Mahalakshmi MDs						
	Designation	Lecturer						
	Affiliation	National Institute of Siddha						
	Address	National Institute of Siddha, Tambaram sanatorium, Chennai-47, Tamil Nadu, - Chennai TAMIL NADU						

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	f	110	600047 ndia					
	Phone	$\overline{}$	9444519975					
	Fax							
	Email	t	vmahalakshmi85@	@gmail.com				
Source of Monetary or	T. Control of the Con	So	urce of Monetary	or Material Su	pport			
Material Support	> National Institute of S		the particular to the second		and the same of th			
Primary Sponsor			Primary Sno	onsor Details	811			
	Name	To	Or Monika M	Dispos Distanto				
	Address			f Siddha, Tamba	aram san	atorium, Chennai-47		
	Type of Sponsor	-	Other []			USANICHEM PROPRIES		
Details of Secondary	Name		ALCOHOL TO	Address				
Sponsor	NIL			NIL				
Countries of	List of Countries			1				
Recruitment	India							
Sites of Study	Market Control	Michigan	of Cito	City Address		Discontinue of the second		
Sites of Study	Name of Principal Investigator	Name	of Site	Site Address		Phone/Fax/Email		
	DrMonikaM	Department of Sirappu Maruthuvam		Ayothidoss pandithar hospital, National Institute of Siddha, Tambaram sanatorium, Kancheepuram TAMIL NADU		8056367363 text2moni@gmail.com		
Details of Ethics Committee	Name of Committee	Approval Status		Date of Approval		Is Independent Ethic Committee?		
	Institutional Ethical Committee	Approved		22/11/2017		No		
Regulatory Clearance	Status			Date				
Status from DCGI	Not Applicable		No Date		pecified			
Health Condition /	Health Type			Condition Other soft tissue disorders				
Problems Studied	Patients							
ntervention /	Туре		Name	Details				
Comparator Agent	Intervention		Vithu Rasa Mez Ennai Varmam	Murivu		Rasa Mezhugu (Internally u Ennai (Externally) um external therapy		
	Comparator Agent		NIL		NIL	11197		
nclusion Criteria			Inclusio	n Criteria	-			
	Age From	12	20.00 Year(s)					
	Age To	6	55.00 Year(s)					
	Gender		Both					
Details			Pain and tenderne	ss, often sudder	and sev	ere in the knee joints		
			Pain get worse while walking					
			a feeling of looseness in the knee joints					
			patient willing to undergo radiological investigations and laboratory investigations					

O E TOTAL STATE

Exclusion Criteria	Exclusion Criteria					
	Details	Complete ligament tear of the knee joint Posterior cruciate ligament tear Evidence of bony fractures in X-rays H/o Cardiac diseases H/o Diabetes mellitus H/o Rheumatoid arthritis H/o Chronic kidney disease Pregnancy and lactation Septic arthritis Gonococcal arthritis Psoriatic arthritis Patient with any other serious systemic illness.				
Method of Generating Random Sequence	Not Applicable					
Method of Concealment	Not Applicable					
Blinding/Masking	Not Applicable					
Primary Outcome	0	utcome	Timepoints			
	To relieve the pain nd it will be assessed by Koos knee survey.		1-48 days			
Secondary Outcome	0	utcome	Timepoints			
	NIL		NIL			
Farget Sample Size		dia=30 mbers achieved (Total)=	Applicable only for Completed/Terminated trials Applicable only for Completed/Terminated trials			
Phase of Trial	N/A					
Date of First Enrollment (India)	27/09/2018					
Date of First Enrollment (Global)	No Date Specified					
Estimated Duration of Trial	Years=1 Months=5 Days=10					
Recruitment Status of Trial (Global)	- International Control of the Contr					
Recruitment Status of Trial (India)	Not Yet Recruiting					
	NIL					
Publication Details	NIL  Primary objective of this study is to evaluate the therapeutic efficacy of siddha drugs Vithu Rasa Mezhugu (internal) and Murivu Ennal (external) in reducing the pain and restricted movements in the treatment of Muzhangal Mootu Savvu Kayangal (Ligament injury-knee joint) with and without varmam through clinical study.					



#### DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG "VITHU RASA MEZHUGU" (INTERNAL) AND "MURIVU ENNAI" (EXTERNAL) IN THE TREATMENT OF "MUZHANGAL MOOTU SAVVU KAYANGAL" (LIGAMENT INJURY-KNEE JOINT).

Principal Investigator: Dr.M.Monika					
FORM I - SCREENING & SELEC	CTION PROFORMA				
1.SERIAL NO: 3. NAME: 5. OCCUPATION:	2. OP /IP NO: 4. AGE/GENDER: 6. INCOME:				
INCLUSION CRITERIA					
<ul> <li>Whether age is 20 to 60 yrs</li> </ul>	YES	NO			
• Sex	$\mathbf{M}ackslash \mathbf{F}$				
• Pain and tenderness, often sudden and severe	-				
<ul> <li>Pain gets worsen while walking</li> </ul>	YES				
<ul> <li>Swelling present in the knee joint</li> </ul>	YES				
<ul> <li>A feeling of looseness in the knee joint</li> </ul>	YES	NO			
<ul> <li>Inability to put weight on the joint without pai</li> </ul>	n YES	NO			
<ul> <li>Patient willing to undergo radiological investig</li> </ul>	gation YES	NO			
<ul> <li>Patient willing to undergo laboratory investigation</li> </ul>	ations YES	NO			
<ul> <li>Patients willing to sign the informed consent s</li> </ul>	tating				
that he/she will conscientiously stick to the tre					
during 48 days but can opt out of the trial of h					
discretion	YES	\NO			
EXCLUSION CRITERIA					
<ul> <li>Posterior cruciate ligament tear</li> </ul>	YES	NO			
<ul> <li>Complete tear of the ligament</li> </ul>	YES	NO			
<ul> <li>H/O cardiac disease</li> </ul>	YES	NO			
<ul> <li>H/O Rheumatoid disease</li> </ul>	YES	NO			
<ul> <li>H/O Chronic kidney disease</li> </ul>	YES	NO			
<ul> <li>Pregnancy and lactation</li> </ul>	YES	NO			
<ul> <li>Septic arthritis</li> </ul>	YES	NO			
<ul> <li>Gonococcal arthritis</li> </ul>	YES	NO			
<ul> <li>Psoriatic arthritis</li> </ul>	YES	NO			
Patient with any other serious systemic illness	YES\NO				
ADMITTED TO TRAIL  YES NO PD IPD Serial NO:					
Date : Station : Signature of the Investigator :					

**Signature of the HOD** 

**Signature of the Lecturer:** 

#### NATIONAL INSTITUTE OF SIDDHA

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

#### **DEPARTMENT OF SIRAPPU MARUTHUVAM**

A DRUG " <i>VITHU RASA MEZHUGU"</i> (INTERNAL) TREATMENT OF " <i>MUZHANGAL MOOTU SAVVU</i> T).
OP / IP NO: AGE / GENDER: CONTACT NO: RELIGION: H/C/M/O.
INCOME:
2. Unmarried

#### 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	1
person(s)	2
DIETARY STYLE:	1. Vegetarian 2. Non-vegetarian

#### MENSTURAL AND OBSTETRIC HISTORY:

#### FORM -II B

GENE	RAL EXAMI	NATION:				
	1. Body weig	ght [Kg]		:		
	2. Height [cr	ns]		:		
	3. Body Tem	perature [F]		:		
	4. Blood Pre	ssure (mm/Hg)		:		
	5. Pulse Rate	e/min.		:		
	6. Heart Rate	e / min.		:		
	7. Respirator	ry Rate /min.		:		
Yes	No					
	8. Pallor			:		
	9. Jaundice			:		
	10. Clubbing			:		
	11. Cyanosis			:		
	12. Pedal Oed	lema		:		
	13. Lymphade	enopathy		:		
	14. Jugular ve	enous pulsation		:		
SYSTI	EMIC EXAM	INATION				
Card	iovascular sys	stem	:			
	iratory system		:			
_	ro-intestinal s		:			
	ral Nervous sy	•	:			
	enital system		:			
_	rine system	:				
	v	CIDDIIA CIA		OF	757 A B #157	TION
		SIDDHA SYS	STEM	OF I	EXAMINA	ATION
1. THI	EGI (BODY C	CONSTITUTIO	ON):			
1. Vath	na udal					
2. Pitha	a udal					
3. Kab	a udal					
4. Tho	ntha udal					
2. NIL	AM (LAND V	WHERE THE	PATI	ENT I	 LIVED M	OST):
1 Kuri	inji (Hilly terra	in)			$\neg$	
	lai (Forest rang				$\dashv$	
	utham (Plains)	• '			=	
	hal (Coastal be				_	
	ai (Coastai be				_	
		)				
	r kaalam	(Aavani-Purat	,			
	thir kaalam	(Ippasi-Kaarth	_			
	npani kaalam	(Maargazhi-T	,			
	ani kaalam	(Maasi-Pangu				
	enil kaalam	(Chithirai-Vai	gasi)			
6. Mut	huvenil kaalan	n (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

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

#### B) AZHAL

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

#### C) IYYAM

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

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

#### I. NAADI: [PULSE PERCEPTION]

NAADI	0 <sup>th</sup> day	8 <sup>th</sup> day	15 <sup>th</sup> day	22 <sup>nd</sup> day	29 <sup>th</sup> day	36 <sup>th</sup> day	43 <sup>rd</sup> day	49 <sup>th</sup> day

#### II. SPARISAM: [PALPATION]

Day	SPARISAM
0 <sup>th</sup> day	
8 <sup>th</sup> day	
15 <sup>th</sup> day	
22 <sup>nd</sup> day	
29 <sup>th</sup> day	
36 <sup>th</sup> day	
43 <sup>rd</sup> day	
49 <sup>th</sup> day	

#### III. NAA: [TONGUE]

NAA	0 <sup>th</sup> day	8 <sup>th</sup> day	15 <sup>th</sup> day	22 <sup>nd</sup> day	29 <sup>th</sup> day	36 <sup>th</sup> day	43 <sup>rd</sup> day	49 <sup>th</sup> day

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1. Vadham	
2. Pitham	
3. Kabam	

1. Hi <sub>2</sub> 2. Lo	HI: [VOIC gh Pitched w Pitched edium Pitch							
VI.VIZH	II: [EYES]	]						
VIZHI	0 <sup>th</sup> day	8 <sup>th</sup> day	15 <sup>th</sup> day	22 <sup>nd</sup> day	29 <sup>th</sup> day	36 <sup>th</sup> day	43 <sup>rd</sup> day	49 <sup>th</sup> day
N	LAM: [BO		ABITS / ST Before tre			After treat	tment	
	llagal Others							
	OOTHIRA	M [URIN	E EXAMI	INATION:				
Neerkkuri Before treatment						After treat	tment	
Niram								
Manam								
Edai								
Nurai								

**Enjal** 

#### **NEIKKURI:**

Neikkuri	Before treatment	After treatment
Aravena neendathu/ Snake like pattern		
Aazhipol paraviyathu Annular/Ringedpattern		
Muththothu ninrathu Pearlbeadepattern		
Other patterns		

#### **CLINICAL EXAMINATION:**

LOCOMOTOR SYS	STEM:			
CLINICAL SYMPT	TOMS:			
Affected knee joint:	Right	Left	Both	
Pain and stiffness				
in knee joint:	Mild	Moderate	Severe	
Onset:	Sudden	Gradual		

#### **CLINICAL EXAMINATION**

#### **I.INSPECTION:**

	0 <sup>th</sup> day	8 <sup>th</sup> day	15 <sup>th</sup> day	22 <sup>nd</sup> day	29 <sup>th</sup> day	36 <sup>th</sup> day	43 <sup>rd</sup> day	49 <sup>th</sup> day
Swelling								
Stiffness								
Gait								

#### **II.PALPATION:**

	0 <sup>th</sup> day	8 <sup>th</sup> day	15 <sup>th</sup> day	22 <sup>th</sup> day	29 <sup>th</sup> day	36 <sup>th</sup> day	43 <sup>rd</sup> day	49 <sup>th</sup> day
Tenderness								
Local heat								

#### III. MOVEMENTS

	0 <sup>th</sup> day	8 <sup>th</sup> day	15 <sup>th</sup> day	22 <sup>nd</sup> day	29 <sup>th</sup> day	36 <sup>th</sup> day	43 <sup>rd</sup> day	49 <sup>th</sup> day
Flexion								
Extension								

#### IV. JOINT MESUREMENT:

#### A. HEALTH ASSESSMENT QUESTIONNAIRE:

	$0^{th}$	8 <sup>th</sup>	15 <sup>th</sup>	22 <sup>nd</sup>	29 <sup>th</sup>	36 <sup>th</sup>	43 <sup>rd</sup>	49 <sup>th</sup>
	day	day	day	day	day	day	day	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 JOINT LIGAMENT EXAMINATION:**

#### 1. Anterior drawer sign:

The anterior drawer test examine for any tearing or laxity of the anterior cruciate ligament.

#### 2. Posterior drawer test:

The posterior drawer test is used to examine the posterior cruciate ligament.

#### 3. Valgus test:

The valgus stress test checks for medial joint laxity, which usually represents an injury to the medial collateral ligament.

#### 4. Varus test:

The varus stress test checks for joint laxity on the outside of the knee, which usually represents an injury to the lateral collateral ligment.

#### 5. McMurray's test:

This test checks for meniscal tears and other internal derangement in the knee.

#### **OUTCOME:**

#### **Primary outcome:**

Primary outcome of the study is pain relieving and it will be assessed by the following methods:

#### **WOMAC - How to score from the KOOS**

Assign scores from 0 to 4 to the boxes as shown above. To get original WOMAC Scores, sum the item scores for each subscale. If you prefer percentage scores in accordance with the KOOS, use the formula provided below to convert the original WOMAC scores.

WOMAC subscores  Pain Stiffness Function	Original score = sum of the following items P5-P9 S6-S7 A1-A17	Maximum score 20 8 68
Date: Station: Signature of the Investigator:		
Signature of the Lecturer:		Signature of the HOD

- actual raw score x 100

maximum score

Transformed scale = 100

#### **DEPARTMENT OF SIRAPPU MARUTHUVAM**

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG "VITHU RASA MEZHUGU" (INTERNAL) AND "MURIVU ENNAI" (EXTERNAL) IN THE TREATMENT OF "MUZHANGAL MOOTU SAVVU KAYANGAL" (LIGAMENT INJURY-KNEE JOINT).

Principal Investigator: Dr.M.Monika

BLOG	OD INVESTIGATIONS	NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Blood	Fasting	70-110		
glucose (mg/dl)	PP	80-140		
RFT	Blood urea	16-50		
(mg/dl)	Serum creatinine	0.6-1.2		
	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-0.2		
	Indirect bilirubin	0.2-0.7		
	Total protein	6-8		
LFT (mg/dl)	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			

1.SERIAL NO: 3. NAME:

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

#### FORM-III - LABORATORY INVESTIGATIONS

BLOOD INVES	BLOOD INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Hb( gm/dl)		M:13-18		
		W:11-16		
T PRC(millions	T.RBC(millions cells /Cu.mm)			
1.Kbc(minions	cens/cu.mm)	W:3.5-5.5		
	½ hr.	•		
ESR (mm)	1 hr.	M:0-10		
	I III.	W:0-20		
T.WBC (Cel	ls /Cu.mm)	4000-11000		
	Polymorphs	40-75		
	Lymphocytes	20-35		
Differential Count (%)	Monocytes	2-10		
	Eosinophils	1-6		
	Basophils	0-1		

#### **B.URINE INVESTIGATIONS:**

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

Albumin			
Sugar (Fasting)			
(PP)			
Deposits			
Bile salts			
Bile pigments			
C.RADIOLOGICAL MRI-KNEE JOINT	EXAMINATIONS		
Date: Station:			
Signature of the Investignature of the Lectu	stigator: rer:	Signature of the H	ΩD

Station:	
Signature of the Investigator: Signature of the Lecturer:	Signature of the HOI

#### DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG "VITHU RASA MEZHUGU" (INTERNAL) "MURIVU ENNAI" (EXTERNAL) IN THE TREATMENT OF "MUZHANGAL MOOTU SAVVU KAYANGAL" WITH VARMA.

Name of Principal Investigator: Dr.M.Monika

#### FORM -IV- DRUG COMPLIANCE FORM

**SERIAL NO:** 

NAME:

**DRUG NAME:** 

On 1 <sup>st</sup> day-Date:	Drugs issued: (mgs)	Drugs returned:	(mgs)
On 8 <sup>th</sup> day-Date:	Drugs issued: (mgs)	Drugs returned:	(mgs)
On 15 <sup>th</sup> day-Date:	Drugs issued: (mgs)	Drugs returned:	(mgs)
On 22 <sup>th</sup> day-Date:	Drugs issued: (mgs)	Drugs returned:	(mgs)
On 29 <sup>th</sup> day-Date:	Drugs issued: (mgs)	Drugs returned:	(mgs)
On 36 <sup>th</sup> day-Date:	Drugs issued: (mgs)	Drugs returned:	(mgs)

Day	Date	Morning	Evening	Day	Date	Morning	Evening
Day 1				Day25			
Day2				Day26			
Day3				Day27			
Day4				Day28			
Day5				Day29			
Day6				Day30			
Day7				Day31			
Day8				Day32			
Day9				Day33			
Day10				Day34			
Day11				Day35			
Day12				Day36			
Day13				Day37			
Day14				Day38			
Day15				Day39			
Day16				Day40			
Day17				Day41			
Day18				Day42			
Day19				Day43			
Day20				Day44			
Day 21				Day45			
Day 22				Day46			
Day 23				Day47			
Day 24				Day48			

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

#### DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG "VITHU RASA MEZHUGU" (INTERNAL) AND "MURIVU ENNAI" (EXTERNAL) IN THE TREATMENT OF "MUZHANGAL MOOTU SAVVU KAYANGAL" (LIGAMENT INJURY-KNEE JOINT) WITH AND WITHOUT VARMAM.

#### **FORM-V-INFORMATION SHEET**

Name of Principal Investigator :Dr .M.Monika

Name of the institute : National Institute of Siddha,

Tambaram Sanatorium,

Chennai-47.

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

I, Dr.M.Monika Studying as M.D(Siddha) at National Institute of Siddha, Tambaram Sanatorium is doing a trial on the study of Muzhangal Mootu Savvu Kaayangal (Ligament injury-knee joint). 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 Vithu rasa mezhugu(Internal medicine- Twice a Day with palm jaggery for 9 days) and Murivu ennai (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 between you and the principal investigator (myself). 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.M.Monika, PG Scholar 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

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#### தகவல் படிவம்

நோய்க்கான சித்த மருந்துகளின் வித்து ரச மெழுகு (உள் மருந்து) மற்றும் முறி வெண்ணெய் (வெளி மருந்து) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர் : மு. மோனிகா

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்

தாம்பரம் சானட்டோரியம்

சென்னை- 47

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர்.மு.மோனிகா) முழங்கால் மூட்டு சவ்வு காயங்கள் என்னும் நோய்க்கான மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இது தோள்பட்டையில் வலி, விறைப்புத்தன்மை, கையை நீட்ட மடக்க முடியாமல் நோதல் முதலிய குறிகுணங்களைக் கொண்ட நோய்

இது பரவக் கூடிய நோய் அல்ல. இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன். இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக வித்து ரச மெழுகு 65mg வெந்நீரில் 2 வேளை (காலை மாலை) உணவுக்குப் பின் 9 நாட்களுக்கு உட்கொள்ள வேண்டும். வெளி மருந்தாக முறிவெண்ணெய் 48 நாட்களுக்கு நோயுள்ள இடங்களில் வெளியே தடவ வேண்டும். வெளி நோயாளர் 7 நாட்களுக்கு ஒருமுறை மருத்துவமனைக்கு வரவேண்டும்.

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.மு.மோனிகா (பட்ட மேற் படிப்பாளர் சிறப்புமருத்துவ பிரிவு) அணுகவும். மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறப்பட்டுள்ளது.

#### DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG "VITHU RASA MEZHUGU" (INTERNAL) AND "MURIVU ENNAI" (EXTERNAL) IN THE TREATMENT OF "MUZHANGAL MOOTU SAVVU KAYANGAL" (LIGAMENT INJURY-KNEE JOINT) WITH AND WITHOUT VARMAM.

Name of Principal Investigator: Dr.M.Monika.

Date:

#### **FORM-VI – CONSENT FORM**

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

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

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

Signature of the participant

In case of illiterate participant

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

Date:

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

Left thumb Impression of the Participant

#### FORM –VI ஒப்புதல் படிவம்

#### ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் முழங்கால் மூட்டு சவ்வு காயங்கள்என்னும் நோயின் ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி:	கையொப்பம்:
இடம்:	பெயர்:

#### நோயாளியின் ஒப்புதல்

மருத்துவ ஆய்வின் என்னிடம் இந்த காரணத்தையும், மருந்தின் தன்மை வழிமுறை பற்றியும், தொடர்ந்து **இயக்கத்தைக்** மற்றும் மருத்துவ எனது உடல் கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் ம<u>ருத்த</u>ுவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்<u>து</u>வரால் விளக்கிக் கூறப்பட்டது.

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

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு முழங்கால் மூட்டு சவ்வு காயங்கள் நோய்க்கான வித்துரச மெழுகு (உள் மருந்து) மற்றும் முறிவெண்ணெய் (வெளி மருந்து) மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

கையொப்பம்:

இடம்:		பெயர்: சாட்சிக்காரர் கையொப்பம்:
		பெயர்:
		உறவுமுறை:
விரிவுரையாளர்	கையொப்பம்:	துறைத்தலைவர் கையொப்பம்

தேதி:

#### DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG "VITHURASA MEZHUGU"(INTERNAL) AND "MURIVU ENNAI" (EXTERNAL) IN THE TREATMENT OF "MUZHANGAL MOOTU SAVVU KAYANGAL"(LIGAMENT INJURY-KNEE JOINT) WITH AND WITHOUT VARMAM.

JOINT) WITH AND WITHOUT VARMAM.	(LIGAMENT INJUNT-KNE
Name of Principal Investigator: Dr.M.Monika	
FORM VII -WITHDRAWAL FO	<u>ORM</u>
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 Reaction Form / Pharmaco Vigilance Form	
Date:	
Station:	
Signature of the Investigator:	
Signature of the Lecturer:	Signature of the HOD

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Name of Principal Investigator: Dr.M.Monika

# FORM VII - A – ADVERSE REACTION FORM / PHARMACO VIGILANCE FORM

SERIAL NO:		
OP/IP NO:		
NAME:	AGE:	GENDER:
DATE OF TRIAL COMMENCEMENT	<b>:</b>	
DATE OF THE ADVERSE REACTION	N OCCUR:	
DESCRIPTION OF ADVERSE REACT	ΓΙΟΝ:	
Date:		
Station:		
Signature of the Investigator:		
Signature of the Lecturer:		Signature of the HOD

#### FORM VII- PHARMACOVIGILANCE/WITHDRAWAL FORM

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

#### NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

#### Reporting Form for Suspected Adverse Reactions to Siddha

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

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

#### Peripheral Center code:

#### State:

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

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

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

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

Medicine Daily Route of		Route of	Date		Diagnosis for
	dose	administration	Starting	Stopped	which medicine
		& Vehicle -			taken
		Adjuvant			
Siddha					
Any other					
system of					
medicines					

4. Brief details of the Siddha Med	dicine which seems	to be toxic :
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Details	Drug – 1	Drug – 2	Drug – 3
a) Name of the medicine			
b) Manufacturing unit			
and batch No. and date			
c) Expiry date			
d) Purchased and			
obtained from			
e) Composition of the			
formulation / Part of the			
drug used			

- b) Dietary Restrictions if any
- c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.
- d) Any other relevant information.
- **5.** Treatment provided for adverse reaction:

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

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

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

- 7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:
- 8. Whether the patient is suffering with any chronic disorders?

Hepatic	Renal	Cardiac	Diabetes	Malnutrition
Any Others				

- 9. H/O previous allergies / Drug reactions:
- 10. Other illness (please describe):
- 11. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient /
Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)

Name:

Address:
Telephone / E – mail if any:

#### Signature of the reporter:

#### Date:

#### Please send the completed form to:

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

The Director

National Institute of Siddha,

(Pharmacovigilance Regional Centre For Siddha

icine),

Tambaram Sanatorium, Chennai-600 047. © (O) 044-22381314 Fax : 044 – 22381314

Website: www.nischennai.org

Email: nischennaisiddha@yahoo.co.in

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

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

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

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Principal Investigator: Dr.M.Monika

#### FORM - VII 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]) முக்கிரட்டை (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), சிறு 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]

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