A CLINICAL STUDY ON SAMUTHRA PAZHA NEI IN THE TREATMENT OF NEER PEENISAM (MAXILLARY SINUSITIS)

The dissertation submitted by

Dr.U. MULLAIKARASI.

P.G. Scholar

Under the Supervision of

PROF. DR. K. MANICKAVASAKAM M.D (S),

Head of the Department of Maruthuvam & Former Director

National Institute of Siddha

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"**A CLINICAL STUDY ON **SAMUTHRA PAZHA NEI** IN THE TREATMENT OF **NEER PEENISAM (MAXILLARY SINUSITIS)"** under the Guidance of **Dr. H. VETHA MERLIN KUMARI, M.D(s), Lecturer** in Department of Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date: Signature of candidate

Place:Chennai-47 (Dr.U.MULLAIKARASI)

CERTIFICATE

Certified that I have gone through the dissertation submitted by Dr. U. Mullaikarasi, (Reg.No: 321411204) a student of Final year MD(S), Branch-I, Department of Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, 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.

Place: Chennai-47

Date:

Name and Signature of the Guide
Dr.H.Vetha Merlin Kumari, MD(S)
Department of Maruthuvm
National Institute of Siddha,
Chennai- 47.

Name and Signature of the HOD
Prof.Dr. K. Manickavasakam, M.D(S),
Department of Maruthuvm,
National Institute of Siddha,
Chennai- 47.

Forwarded by the Head of the Institution
National Institute of Siddha,
Tambaram Sanatorium,
Chennai- 47.

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INDEX

INTRODUCTION

INTRODUCTION

Sinusitis affects a tremendous proportion of the population, accounts for million of visits to primary care physicians each year and in the fifth leading diagnosis for which antibiotics are prescribed accounting for 0.4% ambulatory diagnosis. According to the National Ambulatory Medical Care Survey (NAMCS) approximately 14%adults report having an episode of sinusitis each year.

Siddha system of medicine has become popular All over the world which ensures prevention and promotion of health/well being through principles of "food is medicine and medicine is food" life style modifications, medication etc., and its uniqueness in treating diseases.

Siddha system is said to have originate from the sage agasthiyar tradition attributes the beginning of the Indian system of medicine to the inspiration given by god to agasthiyar who was specially deputed to cure mankind of the numerous ills and diseases.

As per agasthiyar Rathina churukam, siddhars classified the diseases into 4448 types on the basis of three humours and signs&symptoms.Among them the diseases of nasal origin are 86 one such disease is peenisam and NEER PEENISAM is one among 9 types of peenisam.

மிகினும் குறையினும் நோய்செய்யும் நூலோர்

வளிமுதலா எண்ணிய மூன்று. - -குறள் 941

Excess or deficit of any action which produces more or less of the three humours beginning with vali(wind) is recokoned by the authors of medical science to cause.

The treatment of siddha medicine is aimed to keeping the three humors in equilibrium and maintenance of seven elements. So proper diet medicine and a disciplined life and advised for a healthy living and to restore equilibrium of humors in diseased condition.

The signs and symptoms of neer peenisam mentioned in yugi vaidhya chinthamani such as headache, lacrimation, nasal block, nasal itching, ear discharge, running nose, cough with expectoration, absence of taste may be correalated with Maxillary sinusitis in modern medicine.

In siddha literature "SAMUTHRA PAZHA NEI" (Ref: Aathi siddha maruthuvam endra Aathmarathachamirtham ennum vaithya saara sangiragam-first edition -2011.,pg no 51)is specified for peenisam which is the approved text book of drug and cosmetic act -1940. The ingredients are Barringtonia *cutangula*,Linn.,Zingiber *officinale*,Rosc.,Allium *sativum*,Linn.,Morringa*oleifera*,Lam.,Plumbago *indica*,Linn., Carum *copticum*,Benth&hook., Piper *nigrum*,Linn., Piper *longum*., Ferula *asafetida*,Linn., Nigella *sativa*,Linn.,Cissus *quadrangularis*,Linn., Navacharam & Inthuppu in the herbo mineral formulation are found to be possess anti inflammatory, anti oxidant, analgesic and anti pyretic actions ,More over the treatment is cost effective and the sastric formulation has not undergone any clinical trial so far.

Hence I have selected SAMUTHRA PAZHA NEI in the treatment of NEER PEENISAM (Maxillary sinusitis).

AIM AND OBJECTIVES

AIM AND OBJECTIVES

AIM

The aim of the study is to evaluate the therapeutic efficacy of a new herbomineral drug **samuthra pazha nei** in the treatment of neer peenisam.

OBJECTIVES

Primary objective

To evaluate the therapeutic efficacy of the siddha drug samuthra pazha nei in reducing the inflammation in neer peenisam (Maxillary sinusitis).

Secondary objective

1. To collect and review the ideas mentioned in the ancient literature about the disease.
2. To study other co factors related to the disease such as age, sex,occupation,family history, dietary habits, socio economic status,habitate etc on the disease
3. To study the disease neer peenisam on the basis of Siddha principles like
    - Uyir thathukal
    - Udal thathukal
    - Envagaithervu
4. To evaluate the biochemical analysis of the trial medicine.

5.To evaluate the physicochemical analysis of the trial medicine.

6. To evaluate the In-vitro Anti inflammatory activity by protein (Albumin) denaturation assay of the trial medicine

REVIEW OF LITERATURE

SIDDHA ASPECT

SIDDHA ASPECTS

Siddha literature specifies the diseases types based on three dhoshas into 4448 types. Among them 1008 types of diseases are classified under head and neck region. Out of which the disease of nasal origin are 86 in number. Peenisam disease is classified into 9 types. Neer peenisam is one among them.

Synonyms

- Neer kovai
- Mookkadaipu
- Mookuneer paichal

Definition :

Characterization of Peenisam are Redness of both nostrils, Redness of both eyes, Burning sensation of both eyes, Increased lacrimation, Headache, Continous sneezing, Rhinorrhoea, Bleeding from the nostril.

கண்ட மெழுகவே தாடை
காகதோ அவதைப் போலத்
துண்டவுந் தினவும் பற்றித்
தும்மியே தண்ணீர் வீழ்ந்து
மண்டையுங் கனத்து நொந்து
வாதமும் பகைக்குமாகில்
முண்டக மதிக்கு மாதே
மூக்குநீர்ப் பாய்ச்ச லாமே. - Agathiyar gunavaagadam

AS PER AGATHIYAR GUNAVAAGADAM

தெரிந்து கொள்வாய் நீர்கோவை ரோகந் தன்னை
திறமாகச் சொல்லுகின்றேன் நன்றாய்க் கேளு
அறிந்து கொள்வாய் தேகத்தின் சவ்விலேனும்
ஆக்கையின் தோலடியிலிருக்கும் சவ்விலேனும்
பரந்து நீர் இரத்தனீர் சேர்வதாலே
பரிவது நீர்கோவை யென்று பேராய்த்

துரந்துமே வெளியாகத் தோற்றலாலே
தொல்லுலகில் அநேகவிதப் பேருமாச்சே
ஆச்சப்பா சிரசில்தான் நீரே கண்டால்
அப்பனே அதற்கு சலமஸ்தக மென்பார்
பேச்சப்பா மார்பில் நீரேற்றங் கண்டால்
புகழான உரோசல ரோகமென்பர். - Agathiyar gunavaagadam

AETIOLOGY :

AS PER AGATHIYAR KANMAKAANDA KOWMATHI NOOL-300

பகருவேன் மண்டையிலே கரப்பான் கட்டும்
பகரரிய பீனிசங்க ளிரணத்தோடு
நிகரில்லா வொருதலைநோய் மண்டைக்குத்தும்
நிசமாக வந்தகன்மம் நிசமாய்க் கேளு
தகரவே காயடித்த லிலைபறித்தல்
தளிர்கொழுந்து தழைமுறித்தல் பட்டைவெட்டல்
நிகரில்லாப் பூப்பறித்தல் வேர்கொடிகள் வெட்டல்
நினைவுகெட்டுச் சீவசெந்து தனையடித்தலாலே.

According to agasthiyar kanmakandam 300, peenisam is considered to be a karma disease. The activities like pluking leaves, fruits, young shoots, flowers, cutting barks, roots, twigs, and hurting animals will cause peenisam.

SIDDHA MARUTHUVAM, ARUVAI MARUTHUVAM, NOI NADAL NOI MUDAL NADAL PART (2)

In the above literatures, the aetiology of peenisam is follows,

- Drinking cold water.
- Exposure to cold.

- Exposure to dust.
- Travel against wind.
- Smelling of Dust particles which induced sneezing.
- Drinking cold water while increased body heat.
- Associated with Mega diseases.
- Control Vomitting and tears.
- Shouted voice.
- Inceased or decreased sleep.

PATHINEN SIDDHAR NAADI SAASTHIRAM & KURUNAADI

பீனிசந்தான் வரலாறு சொல்லக் கேண்மின்
சேதமுடன் கனலெழும்பு வாய்வு சேர்த்து
ஊறுருதி மண்டையிலே தொடுக்கப்பட்டு
உறுதியுடன் வாயுகங்கே யுறுத்துபின்னும்
ஈனமுடன் நோடும் நீர்சீ ழிரத்தம்
பிடித்து கருங்காது மூக்கி னோடு
தேனருவி வந்தனு போல் செங்கண் சீருயர்
சேர்ந்து வீழும் பீனிசத்தின் செய்கையாமே.

The heat and vayu continue together and affect the head, thereby causing peenisam

JEEVARATCHAMIRTHAM (NASIGA ROGA PETHAM)

The literature describes the below etiological features:

- Exposure to cold air
- Nasal blockage by dust
- Loud speech
- Excess sleep or sleeplessness.
- Taking bath in cold water daily
- Controlling the urges and tears

- Sleeping in uneven bed
- Excessive sexual indulgence.

T.V SAMBASIVAM PILLAI MARUTHUVA AGARATHI:

- Mucous discharge through the nostrils is due to an inflammation in the head or cold affecting in the nose.
- Excessive indulgence in sexual intercourse
- Body heat is transmitted to head
- Entry of minute particle of dust or smoke into the nostrils
- Excessive application of heat or cold
- Voluntary retension of stools and urine
- Diseases of the nose

CLINICAL FEATURES:

Asper yugimuni vaithya kaaviyam

Neer peenisam Gunam:

சத்தே யிருமல் தும்மல்வரும் ஜலமாய் மூக்கில் நீர்பாயும்
முத்தேபிடரி முடியிகட்டி மொருக்கலண்டி பிரண்டியிருக்கும்
மற்றவியாதிக் கிடங்கொடுக்கும் மாகில் கோழைமரித்து விழும்
நித்தம் நோய்கள் நிறைந்திருக்கும் நீர்பீனிசமுமெனலாமே.

தலையும் வலித்திட்டொரு நாசி சளியே விழுந்துவொடுவுண்டாய்
வலையும் அந்நாளேழு சென்றால் வரண்டுஇருகித் திரண்டுவிழும்
வலையுமிக வுநாற்றமதாய் யுண்டதண்ணீர் விழுந்திருக்கும்
பிலமுஞ் செய்து நாசியடைக்கும் பீனிசத்தின் குணமிதுவே.

Cough with expectoration, sneezing, running nose, pain in the occipital region which persists throughout the days.

AS PER AATHMA RATCHAMIRTHAM

சிரசில் கனலெழுந்து சூலையில் ரோகம்
அதிகரித்து சீழ்போலும் சிராய் போலும்
காணப்படும் ஒருவித மூக்கு நோய்.

Increased heat affects head causing pain and purulent discharge from the nose.

NAGAMUNIVAR THALAI NOI MARUTHUVAM AND SIDDHAR ARUVAI MARUTHUVAM:

தலைமிக வலிக்கும் நாசி சளிவிழுமொருவுண்டாகும்
நலிவுரு தும்மலுண்டான் நாட்செவியில் வரளும்நாசி
மலைவுறத் திரண்டு விழும் வாயுவே நாளைமுண்டால்
பெலமுற மூக்கடைக்கும் பீனிச மென்று தேரே.

தலையுங் கனத்து வலிகொண்டு சளிபோனா சாற்றிரண்டு விழும்
அலையு மொருப்போ லொருகாலு மறுதிப் படவே மாறாது
குலையுங் கெடாது பரிகார நியதிப்படவே செய்துவரில்
தொலையுஞ் சொன்னோம் பீனிசமும்.

- Severe headache
- Rhinitis
- Sneezing
- Dryness of nose
- Halistosis
- Severe nasal block
- Headache
- Expectoration

AS PER AGASTHIYAR 2000

கண்ட முகங்கா துங்கரங் தூர்வது போலத்
துண்டமுந் தினவும் பத்தி தும்மியே தண்ணீர் வீழ்ந்து
மண்டையுங் கனத்து நொந்து வாதமும் பகைக்ககுமாகில்
முண்டகமதிக்கு மாதே நீர்பாய்ச்சலாமே.

- Throat, ear and facial irritation
- Itching in the nose
- Rhinitis
- Sneezing
- Heaviness of head
- Headache

NOI NAADAL NOI MUDHAL NADAL PART-2

- Itching and irritation in the nose results in rubbing the tip of the nose which becomes marked red, tense, tender.
- Redness and lacrimation of eyes
- Nasal obstruction
- Itching and blockage of ears
- Difficulty in breathing
- Profuse watery discharge from the nose
- headache

AS PER AGASTHIYAR GUNAVAGADAM

தலையுங் கனத்துவொரு நாசி
சளியும் விளைந்து வொருப்பட்டு
அலையும் நானே யென்சொன்னால்
அரண்டே யிறுகித் திரண்டுவிழும்
உலையு மிகவும் நாற்றமதாய்
ஊடைத் தண்ணீர் விளைந்துவரும்
பிலமுஞ் சேர மூக்கடைக்கில்
பீனிச மென்றார் பெரியோரே. – Agasthiyar Gunavagadam

AS PER THERAIYAR SEKARAPPA

மூக்கு நோயின் பண்பு

பீனச மான பிணிக்கண மெல்லா
மான திறத்தை யறைந்தது போக
வூனமி லாலுரைத்த மருந்தை
நானவில் கின்றன நானிலமீதே
எண்டின முற்ற விரண்டு தரந்தான்
பண்டுள தாகுமற் பங்கினத்தானந்
திண்டிற லேகாடு செய்திறலற்றான்
மண்டை வறண்டு மலிந்திடு நோயே
நோய்களெ லாமிது நோயென வாடும்
பேயென வாடிய பீனிசநோய்கள்
சீயறல் கோணிதஞ் சிட்டிவை நான்கு
மோய்தர மூக்கை யொறுக்குமிதையா
காய்தலிலாப் தகை கண்டசவத்தை
யோதலிலாதிடை யுண்டசலத்தால்
வேதலிலாப்பிணி வேதனையாக்கி
பேதலாகிய பீனிசமாமே.

Lack of taking oilbath twice in eight days leads to dryness in the head causing purulent, watery or blood discharge from nose and nasal block. Drinking unboiled water and contaminated water will cause peenisam.

CLASSIFICATION

As per Aathma ratchamirthamennum vaithiya saara sangiragam

காப்பான வாதபீ னிசந்தானாகும்
கருதியே கோ ரயிந்த பீனிசமுமாகும்
வாப்பான சிலேத்மபீ னிசமுமாகும்

வடுத்த நீர்ப் பீனிசமாம் சீப்பீனிசம்
சேப்பான வுதிரபீ னிசமுமாகும்
செழிப்பான சிறாப் பீனிச மூலப்பீனிசமாம்
ஆப்பான கணபீனிசந்தா னாகும்
அப்பனனே யெட்டு பித் திண்ணமாமே.

1. Vaatha peenisam
2. Pitha peenisam
3. Silethma peenisam
4. Ratha peenisam
5. Seezh peenisam
6. **Neer peenisam**
7. Sirap peenisam
8. Moola peenisam

According to Maruthuvam and noinadal noi mudhal nadal part 2 peenisam is of 9 types.

1. Vali peenisam
2. Azhal peenisam
3. Kapha peenisam
4. Kuruthi peenisam
5. **Neer peenisam**
6. Seezh peenisam
7. Sirai peenisam
8. Mulai peenisam
9. Kazhuthu peeenisam

According to thanvandri vaithiyam peenisam is of 10 types.

1. Vatha peenisam
2. Pitha peenisam
3. Kapha penisam
4. Vathapitha peenisam
5. Vatha kapha peenisam
6. Pithakapha peenisam

7. Mukutra peenisam
8. **Sala peenisam**
9. Ratha peenisam
10. Varatchi peenisam.

According to T.V sambasivam pillai maruthuva agarathi peenisam is of 7 types.

1. Vatha peenisam
2. Pitha peenisam
3. Silethma peenisam
4. Seezh peenisam
5. Sirai peenisam
6. **Neer peenisam**
7. Ratha peenisam

Mukutra vaerupadugal:

- Due to food habits and deranged pitham i.e; pitham raised from its nature which body heat raises which inturn increases both vatham and kabam.
- When doing yoga, the vitiated pitham along with udhana vayu reaches the head where it combines with kabam causes peenisam.

NAADINADAIINPEENISAM

Pithathil Sethuma Naadi:

பண்பான பித்தத்தில் சேத்தும நாடி
பரிசித்தா லத்திசுர மிளைப்பு ஈளை
கண்காது நயனமலம் நீருமஞ்சள்
கனவயிறு பொருமல் மஞ்சள்நோய் கண்னோய்
உண்போது மறுத்தல் இரத்த விப்புருதி தானும்
உளைமாந்த பீனிசமும் இரத்த வீக்கம்
நண்பான காமாலை சோகை வெப்பு
நணுகிவந்த பலபிணியும் நண்ணுந்தானே - Sathaga naadi

Sethumathil vaatha naadi:

கண்டாயோ சிலேற்பனத்தில் வாதநாடி
கலந்திடுகில் வயிறு பொருமல் கனத்த வீக்கம்
உண்டாயோ ஓங்கார சத்தி விக்கல்
உறுதிரட்சை வாய்வுவலி சந்தி தோடம்
விண்டாலே இளைப்பிருமல் சோபை பாண்டு
விடபாகம் விடசூலை பக்கவாதம்
திண்டாடு நாசிகாபீடங் கக்கல்
சிரநோய்கள் பலவும்வந்து சிக்குந் தானே. - சதக நாடி

PINIYARI MURAIMAI

The method of diagnosis in siddha system based on,

- Poriyalarithal
- Pulanalarithal
- Vinathal

Porigal are considered as the five sense organs of perception namely nose, tongue, eye, skin and ear.

Pulangal are five senses namely touch, smell, sound, taste and sight sensation. Physiciansuse their pori and pulan to examine the pori and pulan of the patient respectively to diagnose the disease.

Vinathal is obtaining the information regarding the history of the diseases, the clinical features etc, from the patient or from immediate relatives who are taking care of him, when the patient is not in a position to speak or if the patient is child.

The above principle corresponds to the methodology of inspection, palpation, and interrogation methods of modernscience in arriving at a clinical diagnosis of the disease.

Siddha system of medicine has developed a unique method of diagnosing the disease is called "**Envagai thervugal"**

Envagai thervugal:

1. **NAADI**

   The three uyirthathukal are formed by the combination

   - Edakalai + Abanan =Vaatham
   - Pinkalai + pranan =Pitham
   - Suzhumunai +samanan = kabam

In neer peenisam the following naadi are seen commonly

1. Pitha kabham
2. Pitha vaatham
3. Kabha vaatham

2. **SPARISAM**

   In the case of neer peenisam, swelling of face is present.

3. **NAA**

   No abnormality was noted in the tongue of neer peenisam patients.

4. **NIRAM**

In neer peenisam skin of the nose appears, reddish in colour due to over sneezing.

5. **MOZHI**

   In neer peenisam ,decreased resonance of voice due to nasal congestion.

6. **VIZHI**

In neer peenisam patients, irritation of eyes, lacrimation and blurring of vision present.

7. **MALAM**

   No abnormality seen in stools.

8. **MOOTHIRAM**

Neerkuri:

The colour of urine of the neer peenisam patients ,was straw colour in general and in some cases it was yellow.

Neikuri

Prior to the day of urine examination for neikuri , the patients is adviced to take a balanced diet and the quantity of food must be proper for this appetite and patient should have a sound sleep.

After waking up in the morning, urine is collected in a glass container and is subjected to analysis without disturbing its nature and the neikuri should be noticed in direct sunlight.

Line of treatment:

In siddha system the main aim of the tratement is removal of udarpini and manapini.

Treatment is not only aimed removal of disease, but also for the preventing the disease and improving the immunity.

This is said as follows:

- Kaappu (Prevention)
- Neekam (Treatment)
- Niraivu (Restoration)

The three humours which are responsible for organization, regulation and integration of the bodily structures and their physiological functions are always kept in a stage of equilibrium by word, thought, deed and food of the individual. The general aetiological factors for constitutional discomfort are said to be caused by incompatible diet, mental and physical activities.

So it is essential to know the disease and the cause for the onset of disease, the nature of the patient, the severity of illness, the seasons and time of the occurance of the diseases must be observed.

The line of treatment consist of,

- Regulation of affected kutram
- Drug for the disease
- Diet restrictions

In case of neer peenisam the medicines should be given to normalize the vitiated kapha and pitham. The ghee base medicines are given to reduce the vitiated pitham.

DIET AND RESTRICTIONS:

Diet should be taken:

- Pepper
- Karisalai
- Thoothuvalai
- Manathakkali
- Murungai
- Karunai
- Nellikai

Diet should be avoided:

- Butter milk
- Ice cream
- Lemon juice

Vegetables like,

- Bottle gourd
- Pumpkin
- Snake gourd

Advices to be followed:

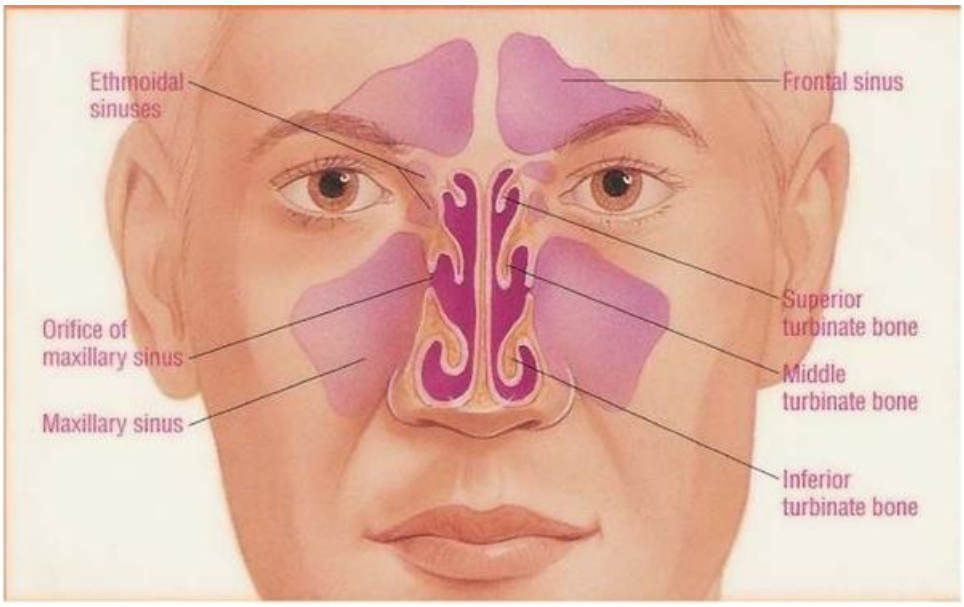
- Avoid polluted places and cold envirionment
- Use hotwater for drinking and sanitary purpose.
- Avoid sleeping during day time.

MODERN ASPECT

MODERN ASPECTS

ANATOMY AND PHYSIOLOGY OF PARA NASAL SINUS

Paranasal sinuses are a group of air containing spaces that surround the nasal cavity.



DEVELOPMENT

Maxillary and ethmoid sinuses are present at birth, while sphenoid sinus is rudimentary at birthand frontal sinus is recognizable at 6 years of age.

Maxillary sinus

It appears an ectodermal depression above the uncinate ridge on inferior turbinate from where it starts expanding laterally and further grows due to spaces vacated by erupting teeth and by 25 years it is fully developed.

Ethmoidal sinus

Small multiple ectodermal evaginations develop on lateral nasal wall and grow laterally into ethmoid bone.

Frontal sinus

It develops from frontal recess at the anterosuperior part of middle meatus which deepens gradually upwards.

Sphenoid sinus

It appears as an ectodermal pit in posterosuperior aspect of nasal capsule and developes by invagination of mucosa of sphenoethmoidal recess. It is the first sinus to reach full size out of all paranasal sinuses.

MAXILLARY SINUSES

It is also called antrum of high more and is the largest sinus in the body of maxilla. It is sometimes referred as conductor of the orchestra. It is a pyramidal in shape, its apex directed laterally into the zygomatic process of maxilla and base forming lateral wall of Nose.

DIMENSIONS

Height 33mm, width 23mm, anteroposteriorly 34mm and capacity varies from 15 to 30 ml.

IMPORTANT RELATIONS OF MAXILLARY SINUS

ROOT

It is formed by floor of orbit traversed by infraorbital canal which transmits maxillary nerve and the vessel from behind forwards.

FLOOR

It lies 1.25 cm below the nasal floor and is formed by alveolar process of maxilla related to 1^{st} premolar to 3^{rd} molar area.

POSTERIOR WALL

Thin plate of bone separating the cavity from pterygopalatine and infratemporal fossa.

Pterigopalatine fossa is a triangular space between maxilla, palatine and pterigoid process of sphenoid, and it contains internal maxillary artery vidian nerve and sphenopalatine ganglion.

ANTERIOR WALL

It is formed by zygomatic process of maxilla, and medially by canine ridge. Infra orbital foramen is closely related to it.

MEDIAL OR NASAL WALL

It is formed by nasal surface of maxilla below and in front. Perpendicular plate of palatine bone posteriorly, and uncinate process of ethmoid bone and descending part of lacrimal bone. Maxillary sinus ostia are 3 to 4 mm in diameter and are situated high up in posterolateral wall and opens in the middle meatus through ethmoidal infundibulam.

In 30% cases, accessory ostium is present which lies slightly posterior to the normal osteum.

LINING OF MAXILLARY SINUS

Pseudostratified columnar ciliated epithelium which is quite thin and relatively less vascular thin with a few mucous glands. It is supplied by branches of maxillary, facial vein and pterygoid venous plexus. Lymphatics drain into submandibular lymph nodes.

NERVE SUPPLY

It is by maxillary nerve through superior alveolar, anterior palatine and infraorbital nerve.secretomotor fibers relay through pterygopalatine ganglion.

FRONTAL SINUSES

These are two in number and are of unequal size divided by a bony septum which is seldom in the midline.

Measurements are: Height 3.16 cm, breadth 2.58 cm and depth 1.8 cm.

The sinus lies behind supercilliary arches and lies in a triangular area formed by nasion, a point 3 cm above nasion and the medial third of the supraorbital margin.

It opens into anterior part of middle meatus either through ethmoidal infundibulam or through frontonasal duct.

IMPORTANT RELATIONS OF FRONTAL SINUS

ANTERIOR WALL

About 1 to 5 mm thick and strong, formed by diploeic bone.

POSTERIOR WALL

It is thin and formed by inner table which separates the sinus from anterior cranial fossa.

FLOOR

It separates the frontal sinus from orbital cavity and slopes downwards towards the opening of frontonasal duct. Superiorly the sinus extends to a variable distance between the outer and inner tablets of the skull.

Supraorbital artery, vein and nerve supply the sinus and lymphatic drainage is the submandibular lymph nodes.

ETHMOIDAL SINUSES

The number varies from 8 to 18, and these within the lateral part of ethmoid bone situated between the nasal cavity and the orbit giving it a honeycomb appearance called ethmoidal labyrinth. Each ethmoidal sinus has a pyramidal shape length is 4 to 5 cm, height 2.5 cm, width is 1.5 cm decreasing anteriorly to 0.5 cm.

Ethmoidal sinuses are divided into two group’s i.e. anterior smaller group consisting of agger cells, buller cells and frontal cells which open into upper part of hiatus semilunaris in the middle meatus, i.e. bulla ethmoidal also called middle ethmoidal groupof sinuses.

Posterior group is larger. It opens into the superior miatus of nose. Optic nerve lies in close proximity to these cells.

IMPORTANT RELATIONS OF ETHMOIDAL SINUS

ROOF

Roof of ethmoidal labyrinth is formed medially by cribriform plate but the main part of the roof is contributed by orbital plate of frontal bone with which ethmoid bone articulates.

FLOOR OF INFERIOR WALL

It is formed anteriorly by orbital plate of maxilla posteriorly by orbital process of palatine bone and is related to maxillary sinus.

LATERAL OR ORBITAL WALL

It is formed by lamina papyracea anteriorly.It is deficient and hence completed by lacrimal bone and posteriorly with lesser wing of sphenoid bone. Lamina papyracea also articulates inferiorly with maxillaand superiorly with the frontal bone.(This suture line is an important landmark as it indicates the roof of ethmoid sinuses in external ethmoidectomy)

It is formed by middle and superior turbinate bones. posteriorlyseparated from the sphenoid sinus by a thin bony septum.

ARTERIAL SUPPLY

Anterior and posterior ethmoidal branches of ophthalmic and sphenopalatine artery. Venous drainage is to the corresponding veins.

NERVE SUPPLY

It is by branches of maxillary nerve and ophthalmic nerve which form the anterior and posterior ethmoidal nerves.

SPHENOID SINUSES

These are contained in the body of sphenoid bone and are situated in the posterior part of nasal cavity. These are rudimentary at birth but to grow after the third year. Its capacity varies from 0.5 to 30 ml with an average of 7.5 ml.

Measurements are: height 2 cm, breadth 1.8 cm, and depth 2 cm. ostium lies in the upper part of anterior wall and opens into sphenoethmoidal recess. Bones of bertin also called sphenoidal turbinates initially cover the anterior wall of sinus, but after 10 years fuse with it.

IMPORTANT RELATIONS OF SPHENOIDAL SINUS

ROOF

It is related with pituitary gland, and opticchiasma. Anterior roof is related to frontal lobe and olfactory tract.

FLOOR

It is related to roof of nasopharnyx and vidian nerve.

ANTERIORLY

It is related to supraorbital fissure, 3^{rd}, 4^{th} and 7^{th} cranial nerves and ophthalmic division of 5^{th} nerve.

POSTERIORLY

Thick wall separates it from pons and basilar artery.

LATERALLY

There is cavernous sinus, internal carotid artery and division of trigeminal nerve.

BLOOD SUPPLY

It is by the posterior ethmoid and sphenopalatine artery. Veins drain into veins of nasal cavity.

NERVE SUPPLY

It is by branches of sphenopalatine ganglion.

LYMPHATICS

They go to retropharngeal lymphnodes.

FUNCTIONS OF PARANASAL SINUS

Air conditioning, i.e. warming and moistening.

Reduction of skull weight.

Increases the olfactory area.(in animals)

Heat insulation.

Vocal resonance.

Provides mechanical rigidity to skull.

Pressure dampening.

Secreation of mucous to keep nasal chambers moist.

Absorption of shock to face and skull during injuries.

Regulation of intranasal pressure.

ACUTE SINUSITIS

It means acute infection or inflammation of the paranasal sinuses of less than 4 weeks duration. It results once the normal defences of mucociliary blanket or lysozymes are breached by viruses and secondary invasion by bacteria takes place.pansinusitis is the term applied to inflammation of all the paranasal sinuses, whereas individual sinus involvement is named accordingly such as acute maxillary sinusitis, acute ethmoiditis, acute frontal sinusitis, acute sphenoiditis in order of occurance.

The sinus is said to be closed if the contained inflammatory exudates cannot escape because the viscosity of the exudates is high, or because the sinus ostium is closed. It is said to be open if ciliary action and overflow permit escape to the exudates from the sinus.

AETIOLOGY

INFECTIONS

Nasal infections

Acute rhinitis associated with common cold spreads to the sinuses by way of their natural ostia which open into the nasal cavity. Foreign bodies in the nose may also set up acute rhinitis and further lead to sinusitis.

Pharyngeal infections

Infections such as tonsillitis and adenoiditis may cause sinusitis in children.

Tooth infections

The 1st and 2nd molar teeth are separated from maxillary sinus by a thin bone,and it may be absent in some cases,therefore chronic dental infections may spread either directly or through lymphatics. periodontal abcess which is an inflammation of the membrane which sorrounds the root of tooth and infection may spread either directly, by lymphatics or through blood stream. Sometimes tooth extraction may lead to infection of maxillary sinus, especially if fracture of tooth occurs during extraction, and it is forced into the antrum.

Swimming and bathing

Swimming and bathing in infected ponds or pools, especially if jumping feet down. Even if water is uncontaminated, chemical rhinitis and sinusitis may be sufficient to cause bacterial sinusitis.

Trauma to the sinuses

- Compound fracture of the sinuses.
- Contusion of the sinuses.
- Foreign bodies.
- Barotraumas of the sinuses during flight travel, especially during the descent of aeroplanes.

General diseases

Such as influenza, measles, whooping cough, and pneumonia may lead to sinusitis.

Other contributing factors

- Poor general environment.
- Low resistance, especially in children with little immunity.
- Undue exposure to crowded cities people.

- Anatomical obstructions such as deviated nasal septum, hypertrophied turbinates, enlarged bulla or enlarged adenoids. Infective and allergic conditions of the nose also lead to mucosal swellings causing obstructions of the natural ostia of the sinuses. Polyp and tumours also cause sinusitis.
- Association with chest conditions, e.g. chronic bronchitis, asthma, bronchiectasis and cystic fibrosis. Kartagener's syndrome include dextrocardia, chronic sinusitis and bronchiectasis and is due to faulty cilia.
- Bacteriology

Bacteria

- Pneumonia (29%)
- Streptococci
- Staphylococci (6.6%)
- H.influenzae (48%)
- Escherichia coli
- Micrococcus catarrhalis
- Bacillus Pfeiffer
- B.freidlander

Viruses

- Rhinovirus.
- Parainfluenza
- Enteric cytopathologic human orphan (ECHO) 28.
- Coxsackie.
- Respiratory syncital virus.

Specific infections

Due to fungi, syphilis, tuberculosis and leprosy.

Pathology

Sinusitis passes through five stages, i.e. catarrheal stage, exudative stage, suppurative stage of complications and stage of resolution. Inflammatory changes include hyperaemia with outpouring of serum and polymorphs associated with local

swelling, redness and oedema. If oedema persist for a longtime, cell degeneration with cloudy swelling and necrotic changes will occur.

Clinically, it may be catarrhal type or suppurative type.

Acute catarrhal type

It is the earliest change in which there is oedema and mucous secretion with a few leucocytes but no destruction of mucous membrane.

Acute suppurative type

There is severe inflammation with leucocytes and pus pouring out with necrosis of mucous membrane or it may become polypoidal.

Clinical features

General symptoms

- Malaise
- Headache
- Fever
- Sore throat
- Facial pain
- Periorbital oedema

Local symptoms

- Feeling of discomfort in postnasal space.
- Nasal obstruction.
- Loss of vocal resonance.
- Lose of sense of smell.
- Nasal or postnasal discharge or drip.
- Cough
- Pain in the sinuses.

Antral pain

It is along the infraorbital margins and referred to upper teeth or gums on affected side.

Ethmoidal pain

It is localized over bridge of nose and inner canthus of eye and is referred to parietal eminence.

Frontal sinus pain

It is localized to forehead and pain is periodical in natire, i.e. starts an hour or two after getting up from bed and vanishes during afternoon.

Sphenoidal pain

It gives rise to occipital or vertical headache and sometimes is referred to mastoid process. Pain may be felt behind the eyeball due to close proximity with 5^{th} nerve.

Signs

Anterior group

Maxillary, anterior ethmoidal and frontal.

Posterior group

Posterior ethmoids and sphenoid.

Anterior group drains into middle meatus, while posterior group drains into superior meatus and sphenoethmoidal recess.

External signs

- Flushing cheek with swelling of cheek which may spread to lower lid in maxillary sinusitis. Upper lid may be swollen in frontal sinusitis.
- Ethmoiditis may give rise to swelling at the inner canthus of same eye.
- Tenderness over the affected sinus.
- Cheek: maxillary sinusitis.
- Floor of sinus: frontal sinusitis.
- Inner canthus: ethmoids.
- Anterior rhinoscopy red, shiny and swollen mucous membrane near the ostium of the sinus, and trickle of pus may also be seen.

Investigations

- Haematology -TLC and DLC are increased.
- Culture sensitivity test for Nasal swab
- Transillumination test.
- Maxillary sinus- absence of infra orbital crescent of light papillary glow absence indicate sinusitis.
- Frontal sinus- transillumination is not very informative.
- X-ray PNS to demonstrate fluid level, pus or opacity.
- CT scan –coronal CT may show thickening of mucosa or opacification with occlusion of maxillary infundibulam.

Complications of acute sinusitis

- Osteomyelitis of maxilla and frontal bone.
- Orbital cellulitis.
- Orbital abcess formation.
- Intracranial complications like cavernous sinus thrombosis, meningitis, and intracranial abcess.
- Chronic sinusitis.
- Middle ear infection.
- Pharngitis.
- Laryngitis / tracheobronchitis.
- Mucocele/pyocele
- Oroantral fistula.

CHRONIC SINUSITIS

It is one of the very commonly seen diseases of the sinuses. Maxillary sinus is most commonly involved. It usually follows acute sinusitis which has not been treated adequately or it may also follow a cold or tooth infection. It is a chronic inflammation of mucous membrane which has resulted in irreversible, usually degenerative, changes. Duration of symptoms is more than 3 months.

AETIOLOGY

Chronic sinusitis follows acute sinusitis, chest conditions such as asthma, chronic bronchitis and chronic bronchiectasis may be responsible for chronic sinusitis.

FACTORS PREDISPOSING TO CHRONIC SINUSITIS

- Anatomical deviated nasal septum
- Kartagener's syndrome
- Hypersensitivity
- Dental sepsis
- Poor resistance
- Alcohol
- dusty envirionment
- Allergy subjects are more prone to secondary bacterial infections. Inflammatory products itself may act as allergens inducing further changes in the mucosa of nose and paranasal sinus.
- Fungi also may be responsible for chronic sinusitis.
- Iatrogenic factors- nasal packing, naso gastric or nasotracheal tubing.

PATHOLOGY

Chronic sinusitis according to histological changes in the sinus mucosa may be as follows.

HYPERTROPHIC SINUSITIS

In this, the inflammation mainly affects the efferent vesssels and lymphatics. Soft tissues are affected secondarily. Initially, there is periphlebitis and perilymphangitis. If repeated attacks occur, the venous and lymphatic changes produce oedema and polypoidal mucous membrane, polypi, oedema of periosteum and rarefaction of bone.

ATROPHIC SINUSITIS

The main change occurs in afferent vessels causing cellular reaction around the arterioles and arteries, and later the vessel wall becomes thickened and narrowed resulting in endarteritis and thrombosis. In this condition usually there ismuch less edema. Both these types hypertrophic and atrophic may occur side by side in the same sinus producing atrophy at one place and polypoidal hypertrophy at a nearby place.

PAPILLARY OR HYPERTROPHIC SINUSITIS

Here occurs metaplasia of ciliated columnar epithelium to stratified squamous type and throughout the papillary hyperplastic epithelial cells or stroma may be seen inflammatory cells. It is a viral infection.

FOLLICULAR TYPE

In this condition, small follicles are seen in the mucous membrane of the sinuses.

GLANDULAR SINUSITIS

In this, the glandular elements increase markedly in the submucosal tissue linining of sinuses.

CLINICAL FEATURES

There are two types of chronic sinusitis.

SIMPLE CHRONIC INFECTIVE SINUSITIS

In this, vasomotor rhinitis and allergy are absent. It usually follows a single or repeated attacks of acute sinusitis.

MIXED INFECTIVE AND VASOMOTOR CHRONIC SINUSITIS

The vasomotor factor is probably primary in most of these patients. A secondary infection results from chronic obstruction of ostium and polyposis or as a sequel of acute infection.

FUNGAL SINUSITIS

Fungal infection occurs mostly in traumatic cases with compound fractures, in uncontrolled diabetics, depilated patients, such as carcinoma, and in patients on immunosuppressants, antibiotics or steroids.

Types of fungal infections may be aspergillosis of sinus, actinomycosis which may result in granuloma of antrum or may be mucormycosis with mucor, rhizopus or absidia species of fungus.

Presentation of fungal sinusitis may be in the form of allergic fungal sinusitis, invasive form, fungal ball or fulminant type of chronic fungal sinusitis.

Treatment may be surgery or antifungal therapy with or without steroids.

CLINICAL FEATURES OF CHRONIC SINUSITIS

NASAL SYMPTOMS

- Nasal obstructions, nasal discharge and postnasal drip due to chronic rhinitis and hypertrophic mucosa of nose, especially the turbinates. The nature of nasal discharge depends upon the type of bacteria.
- Postnasal drip is the commonest and most annoying symptom giving rise to dryness and burning at the back of nose together with an unpleasant taste in the mouth.
- Epistaxis due to inflammatory vasodilators.
- Smell abnormalities- cacosmia, hyposmia or parosmia.
- Vestibulitis or excoriation of skin of nose may be present.

PHARNGEAL SYMPTOMS

- Pharyngitis
- Dryness of throat
- Tonsillitis
- Lymphadenitis.

EAR SYMPTOMS

Signs and symptoms of Eustachian tube obstruction or even otitis media.

HEADACHE

Periodicity of headache is due to secretions accumulating in the sinuses during night and then draining away as the patient takes up erect posture. Different pain areas are noticed in involvement of various sinuses.

EYE SYMPTOMS

Conjunctivitis.

RESPIRATORY SYMOTOMS

- Cough.
- Hoarseness of voice.

OTHER SYMPTOMS

- Low grade gastritis with nausea.
- General ill health and tiredness.
- Fever off and on.

SIGNS

ANTERIOR RHINOSCOPY

It shows red swollen mucosa with pus in the middle meatus which can be made to appear by putting the head between the knees with infected sinus upward and then raising the head again.

In ethmoiditis, the middle turbinate may be hypertrophied and polyp may be present.

In sphenoid sinusitis, the pus may be seen in the olfactory cleft.

POSTERIOR RHINOSCOPY

Pool of pus in the upper surface of palate indicates infection of anterior group of sinuses, and even pus at the posterior end of inferior turbinate is pathgnomic of anterior group of sinuses involvement.

EXAMINATION OF PHARYNX

Pus may be seen in the lateral pharyngeal gutter,swelling of the lateral lymphoid tissue, but a trickle or curtain of pus in the posterior wall suggests infection of sphenoid or posterior ethmoidal cells.

INVESTIGATIONS

Besides routine tests like Total Leucocyte count, Differential count, Eosinophil count, urine examination, and culture sensitivity of Paranasl discharge including examination for fungal cytology and Potassium hydroxide staining other investigations include the following.

TRANSILLUMINATION TESTS

They are done for maxillary and frontal sinuses by a special torch in a darkened room. They are 15% less accurate than x-.rays.

X-RAY EXAMINATION OF SINUSES

Occipitomental or water'view.

CT-SCAN OF NOSE

Especially osteomeatal complex.

SINUS SOUNDING OR PUNCTURE OF THE SINUS

It is more appropriately carried out for maxillary sinus, sphenoid and ethmoidal sometimes. Remember for puncturing the sphenoid, anterior wall of sphenoid is situated at 7 cm from anterior nasal spine. Vomerine ridge on septum also leads to the rostrum of sphenoid crossing the centre of middle turbinate.

DIAGNOSIS AND ASSESMENT

Signs and symptoms, proof puncture, and radiography rarely leave any doubt in diagnosis. Bacteriological state should be assessed. The presence of any predisposing factor, such as infected teeth, Deviated nasal septum and nasal polyp should be noted. Length of time of signs and symptoms and treatment taken in the past should be noted as these help to decide the future line of management of the case.

COMPLICATIONS OF CHRONIC SINUSITIS

- Thrombophlebitis of diploeic veins leading to infection of the bone marrow.
- Embolism
- Perivascular lymphatics
- Perineural sheath

COMPLICATIONS OF ANTERIOR GROUP

- Orbital complications, e.g. orbital cellulitis/abcess.
- Mucocele/pyocele
- Fistulae
- Intracranial complications like thrombophlebitis, brain abcess, extradural abcess, and basal meningitis.
- Osteomyelitis of bone
- Pott's puffy tumor – described by sir pericivall pott in 1760, it is doughy swelling of forehead due to osteomyelitis of frontal sinus which gives mouse eaten appearance on X-rays.

COMPLICATIONS OF POSTERIOR GROUP

- Superior orbital fissure syndrome /orbital apex syndrome
- Cavernous sinus thrombophlebitis
- Oroantral fistula /sublabial fistula.
- Optic neuritis with impaired vision.

MATERIALS AND METHODS

MATERIALS AND METHODS

STANDARD OPERATING PROCEDURE FOR "SAMUTHRAPAZHA NEI":

Required raw drugs:

I

01. SAMUTHRA PAZHAM(Barringtonia *acutanguala*)-350 g(10 palam)

02. INJI (Zingiber *officinale,Rosc.*) -350 g (10 palam)

03. VELLULLI (Allium *sativum, Linn.*) -350 g (10 palam)

II

04. MURUNGAI VER(Moringa *oleifera,Lam.*) -10.2g (2 kalanju)

05. KODIVELI VER (Plumbago *indica,Linn.*) -10.2g (2 kalanju)

06. OMAM (Carum *copticum, Benth&hook*) -10.2g (2 kalanju)

07. INTHUPPU (Rock *salt*) -10.2g (2 kalanju)

08. CHUKKU(Zingiber *officinale,Rosc*)

09. MILAGU(Piper *nigram,Linn*) -10.2g (2 kalanju)

10. THIPPILI (Piper *longum*)

11. KAYAM (Ferula *asafoetida,Linn.*) -10.2g (2 kalanju)

12. SEVVIYAM (Piper *nigram,Linn.*) -10.2g 2 (kalanju)

13. NAVACHARAM(Ammoni chloridum) -10.2g (2 kalanju)

14. KARUNCHEERAGAM(Nigella *sativa,Linn.*) -10.2g (2 kalanju)

15. PULIYA MADAR KILANGU -10.2g (2 kalanju)
(PIRANDAI – Cissus *quadrangularis*)

III

16. GHEE -2.6 lit (2 padi)

SOURCE OF RAW DRUGS:

The above said raw drugs will be purchased from a well reputed country shop at Chennai. The raw drugs will be authenticated by Botanist NIS, Pharmacognist SCRI Arumbakkam, Chennai. The raw drugs will be purified and the medicine will be prepared as per SOP as in the Gunapadam Laboratory of NIS, Chennai.

PURIFICATION OF TRIAL DRUGS:

(Ref: 1. Deva Aasirvatham Samuel M.D(S), Marunthu sei iyalum kalaiyum, Indian medicine and Homeopathy, Chennai.

2. Sigicharathana deepam,Kannusami pillai, first edition 2007.)

1. Samuthra pazham (dry fruit of Barringtonia *acutanguala*)

   Clean and Dry under shadow

2. Inji (Rhizome of Zingiber *officinale,Rosc.*)

   Peel the outer covering

3. Vellulli (Rhizome of Allium *sativum, Linn*)

   Peel the outer covering

4. Murungai ver (Root of Moringa *oleifera,Lam.*)

   Clean and Dry under shadow

5. Kodiveli vaer(Root of Plumbago *indica,Linn.*)

   Boil with cow milk and dry under shadow.

6. Omam(Seed of Carum *copticum, Benth&hook*)

   Soak in limestone water for 3 hours and dry

7. Indhuppu(Rock *salt*)

   Soak in goat urine for 45 minutes and dry under sunlight.

8. Chukku(Rhizome of Zingiber *officinale,Rosc*)

   Peel the outer covering and Soak in limestone water and dry

9. Milagu (Dry fruit of of Piper *nigram,Linn*)

   Soak in amla juice and dry

10. Thippili(Dry fruit of Piper *longum*)

    Soak in lemon juice and dry

11. Kayam(Gum-resin of Ferula *asafoetida,Linn.*)

    Clean and fry gently

12. Sevviyam(Root of Piper *nigram,Linn*)

    Soak in amla juice and dry

13. Navacharam(Ammonium chloridum)

    Mix well with cow urine, filters it. Then boil and dry under sunlight.

14. Karuncheeragam(Seed of Nigella *sativa,Linn.*)

    Clean and Dry under sunlight for 6 hours and fry gently

15. Puliyamadar kizhangu(Root tubers of PIRANDAI – Stem of Cissus *quadrangularis*):

Peel the outer covering and soak in butter milk for 3days and dry under sunlight.

METHOD OF PREPARATION:

Step 1:

Ingredient I is boiled with 16.1 lit of water and reduced to 4 lit.

Step 2:

Ingredients II are ground and added to the above water mixture. Finally add ghee and boil till it reaches kudinei concistency (Sigicharathana deepam,Kannusami pillai, first edition 2007) as per siddha text. The prepared drug will be dispensed in sachets (64 ml each) once in 8days for 48 days. At each visit the patients will be advised to return the unconsumed drug if any.

SUBJECT SELECTION

As and when patients reporting at OPD of Department of Maruthuvam Ayothidass Pandithar Hospital with symptoms of inclusion criteria will be subjected to screening test & documented using screening proforma.

INCLUSION CRITERIA

- **Age** :18-50Yrs
- **Sex** – Both male & female
- The symptoms of pain in the face, purulent nasal discharge, and headache/heaviness of head, sneezing, fever, tooth ache, nasal block, and presence of any three symptoms will be taken as inclusion criteria.
- Patient who are willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 24 days but can opt out of the trial of his/her own conscious discretion.
- Patients who is willing for radiological investigation (X-ray for Paranasal sinuses) and provide blood, urine for lab investigation.

EXCLUSION CRITERIA;

- ✓ Bronchial asthma
- ✓ Tuberculosis
- ✓ Diabetes mellitus

- ✓ Hypertension
- ✓ Pregnancy & Lactation
- ✓ Heart disease
- ✓ Chronic obstructive pulmonary disease

WITHDRAWAL CRITERIA

- ✓ Intolerance to the drug & development of adverse reactions during drug trial.
- ✓ Poor patient compliance & defaulters.
- ✓ Patient turned unwilling to continue in the course of clinical trial.
- ✓ Increase in severity of symptoms.

TEST & ASSESSMENTS

CLINICAL ASSESSMENT

SIDDHA ASSESSMENT

ROUTINE INVESTIGATION

SPECIFIC INVESTIGATION

Clinical Assessment:

1. Sneezing
2. Rhinorrhoea
3. Headache/fasial pain
4. Nasal obstruction
5. Post nasal dripping
6. Fever
7. Heaviness of head while bending forward
8. Tooth ache (most involving upper molar teeth)
9. Halitosis
10. Lacrimation
11. Nasal block
12. Redness of eyes
13. Burning sensation of nose
14. Absence of taste.

SIDDHA ASSESSMENT:

Thinai (Living Place)

1. Kurinchi (Hill areas)
2. Mullai (Forest)
3. Marutham (Fertile land)
4. Neithal (Costal area)
5. Paalai (Desert)

Paruva Kalam (season)

1. Karkaalam (Aug 18 – Oct 17)
2. Koothir kaalm (Oct 18 – Dec 16)
3. Munpani kaalm (Dec 17 – Feb 12)
4. Pinpani kaalam (Feb 13 – April 13)
5. Ilavenil kaalam (April 14 – June 14)
6. Muthuvenil kaalam (June 15 – Aug 17)

Iymporikal:

1. Mei (Skin)
2. Vaai (Tongue)
3. Kan (Eye)
4. Mooku (Nose)
5. Sevi (Ear)

UYIRTHATHUKKAL:

Vatham:

1. Praanan
2. Abaanan
3. Samaanan
4. Udhaanan
5. Viyaanan
6. Naagan

7. Koorman
8. Kirukaran
9. Dhananjeyan
10. Devathathan

Pitham:

1. Anarpitham
2. Prasakam
3. Saathakam
4. Aalosakam
5. Ranjakam

Kabam:

1. Avalambagam
2. Kilethagam
3. Santhigam
4. Tharpagam
5. Pothagam

En Vagai Thervu (Eight types of Examination):

1. Nadi (Pulse perception)
2. Naa (Tongue)
3. Niram (Complexion)
4. Mozhi (Voice)
5. Vizhi (Eyes)
6. Sparisam (Palpatory perception)
7. Malam (Bowel habits)
8. Moothiram (Urine) Neerkuri& Neikuri

ROUTINE INVESTIGATION

Haematology

- Hb (gms%)
- Total WBC Count(cells/cumm)
- DC
  - Polymorphs(%)
  - Lymphocytes (%)
  - Eosinophils (%)
  - Monocytes (%)
  - Basophils (%)
- Total RBC count (cells/cu.mm)
- ESR(mm/hr)

BLOOD BIOCHEMISTRY

- Fasting and postparandial Blood sugar

CLINICAL BIOCHEMISTRY

Renal Function Test

- Blood urea (mg/dl)
- Sr. creatinine (mg/dl)
- Uric acid (mg/dl)

Lipid Profile

- S. Total cholesterol (mg/dl)
- HDL (mg/dl)
- LDL (mg/dl)
- VLDL (mg/dl)
- TGL (mg/dl)

Liver Function Test

- S. Total bilirubin (mg/dl)
- S. Direct bilirubin (mg/dl)
- S. Indirect bilirubin (mg/dl)
- SGOT (U/dl)
- SGPT (U/dl)
- S. Alkaline phosphatase (U/dl)
- S. Total protein (g/dl)
- S. Albumin (g/dl)
- S. Globulin (g/dl)

Other Test

- S. Calcium (mg/dl)
- S. Phosphorous (mg/dl)

URINE EXAMINATION

- Neerkuri and Neikuri
- Albumin
- Sugar (Fasting & postprandial)
- Deposits

SPUTUM - AFB

Radiological Investigation

X - Ray for Para nasal sinuses

SPECIFIC INVESTIGATIONS

1. Erythrocyte sedimentation rate (ESR)
2. Absolute eosinophil count (AEC)

STUDY ENROLLMENT

In this open clinical trial study, patients reporting at the OPD with the clinical symptoms of sneezing, headache, running nose, nasal block, fever, tooth

pain, will be examined clinically will be enrolled in the study based on the inclusion and exclusion criteria.

The patients who are to be enrolled would be informed (Form IV) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them

After ascertaining the patient's willingness, informed consent would be obtained in writing from them in the consent form (Form IV A).

All these patients will be given unique registration card in which patient's registration number of the study, address, phone number and investigator's phone number etc. will be given, so as to report easily should any complication arise.

Complete clinical history, complaints and duration, examination findings-- all would be recorded in the prescribed Proforma in the history and clinical assessment forms separately. Screening Form- I will be filled up; Form I-A, Form –II and Form –III will be used for recording the patients' history, clinical examination of symptoms and signs and laboratory investigations respectively.

Patients would be advised to take the trial drug and appropriate dietary advice (Form IV-E) would be given according to the patients' perfect understanding

CONDUCT OF THE STUDY:

The trial drug"SAMUTHRAPAZHA NEI" (Internal) will be given continuously for 48 days. For OP patients, they should visit the hospital once in 8 days. At each clinical visit clinical assessment is done and prognosis is noted. Laboratory investigations & radiological investigation will be done on the 0th day & 48th day of the trial. After the end of the treatment also, the patient is advised to visit the OPD for another 2months for follow-up. If any trial patient who fails to collect the trial drug on the prescribed day but wants to continue in the trial from the next day or two, he/ she will be allowed, but defaulters of one week and more will not be allowed to continue and be withdrawn from the study with fresh case being inducted.

DATA MANAGEMENT

After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever study patient visits OPD Br I during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form . The screening forms will be filed separately.

The Data recordings will be monitored for completion by HOD and adverse event by Pharmacovigilance Department of National Institute of Siddha. All forms will be further scrutinized in presence of Investigators and Sr.Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased reports.

DATA ANALYSIS:

All collected data will be entered into the computer and manually cross checked the correctness of the data entry. The clinical symptoms and laboratory investigation of blood and urine will be analyzed by comparing the two point of data (before and after treatment) paired test and chi-square test will be employed to study the efficacy of treatment. Further the effect of co factors case, occupation, socio economic status, etc will be also be statistically analyzed.

OUTCOME:

(i) Primary outcome:

The outcome is mainly assessed by laboratory and clinical symptom scoring.

s.no	LAB&CLINICAL SYMPTOMS	SCORE
1	X ray of para nasal sinuses	3
2	Rhinorrhea	3
3	Nasal obstruction	3
4	Sneezing	3
5	Facial pain / Head ache	3
6	Post nasal dripping	3

PATIENT CONDITION	
TOTAL COUNT	18
MILD	6/18
MODERATE	12/18
POOR	18/18

(ii)Secondary outcome:

1. To collect and review the ideas mentioned in the ancient literature about the disease.
2. To study other co factors related to the disease such as age, sex,occupation, family history, dietary habits, socio economic status, habituate etc on the disease
3. To study the disease Neer peenisam on the basis of siddha like

Uyir thathukal

Udal thathukal

Envagaithervu

4. To evaluate the biochemical analysis of the trial medicine.

5. To evaluate the physiochemical analysis of the trial medicine.

6. To evaluate the In-vitro Anti inflammatory activity by protein (Albumin) denaturation assay of the trial medicine

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reaction, he/she would be immediately referred to pharmacovigilance Department of NIS, and proper management will be given in OPD of National institute of siddha.

ETHICAL ISSUES

1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipments will be used.

2. No other external or internal medicines other than the trial drugs will be used. There will be no infringement on the rights of patient.

3. The data collected from the patient will be kept confidentially. The patient will be informed about the diagnosis, treatment and follow-up.

4. Aftergetting the consent from the patient (through consent form) they will be enrolled in the study.

5. Informed consent will be obtained from the patient explaining in the understandable language to the patient.

6. Treatment would be provided free of cost.

7. In conditions of treatment failure, adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care throughout the end.

8.The patients who are excluded (as per the exclusion criteria) are given proper treatment in Ayothidoss Pandithar Hospital, National institute of siddha.

DATA COLLECTIONS FORM

- **FORM I SCREENING AND SELECTION PROFORMA**
- **FORM II CLINICAL RESEARCH FORM**
- **FORM lll LABORATORY INVESTIGATION ON ENROLLMENT AND CONCLUSION OF TRIAL**
- **FORM IV DRUG COMPLIANCE FORM**
- **FORM V PATIENT INFORMATION SHEET**
- **FORM VI PATIENT CONSENT FORM**
- **FORM VII WITHDRAWAL FORM / ADVERSE REACTION FORM / PHARMACOVIGILENCE FORM**
- **FORM VIII DIETARY ADVICE FORM**

DRUG REVIEW

DRUG REVIEW

SAMUTHRA PAZHAM

Botanical Name	:Barringtonia *acutangula*,Linn.
Sanskrit name	:Hijjal, vidula,and Ambuj.
English name tree,	:Fresh water mangrove, itchytree, and mango-pine, fish killer
Tamil name	:samuthra pazham.
Other names	: Thathri pala, kadambu, Indian oak,
Family	: Lecythidaceae.
Parts used	:Dry fruit.
Actions inflammatory.	: Anti pyretic, Anthelmintic, Expectorant, Analgesic, Anti
Taste	:sweet, sour and bitter.
Potency	: Hot.
Division	:pungent.
Phytochemicals	**:**Barringtogenol C, Barringtoside A, Barringtoside B & C

GENERAL CHARACTER:

அறிந்திடும் யிளைப்பு காயம் அடர்வலி நாசிநீரு
பறிந்திடும் உதரவாயு நீரிழிவு குன்மம்
சேர்ந்திடும் மண்டை ரோகம் **பீனிசம்** நாசிப்புற்று
அறந்திடும் சமுத்திராப்பழத்தின் தன்மை செய்யே. –Pathartha guna chinthamani

Medicinal uses:

Research on this plant has reported a number of medicinal uses, including antitumor (Seed extract), anti biotic, inhibition growth oh Helicobacter pylori, anti-nociceptive activity and antifungal activity.

INJI

Botanical name : Zingiber *officinale*,Rosc.

Sanskrit name : Adrakam

English name : green ginger.

Tamil name : Inji

Other names : Allam, Aarthragam, Aathiragam, Illakkottai, Narumarupu mathil.

Family : Zingiberaceae

Parts used : Rhizome

Actions :Carminative, Stimulant, Anti inflammatory, Analgesic, Immuno modulatory, Anti viral, Anti bacterial.

Taste :Pungent

Potency :Hot

Division :pungent

GENERAL CHARACTER:

இஞ்சிக் கிங்குக் கிருமல்யம் ஒக்காள்ம்
வஞ்சிக்குஞ் சன்னிசுரம் வன்பேதி-விஞ்சுகின்ற
சூலையறும் வாதம்போந் தூண்டாத தீபனமாம்
வேலையுறுங் கண்ணாய்-விளம்பு.

(அகத்தியர் குணவாகடம்)

ஓதுமே இருமல் சன்னி உறுசேர்ப்பம் சர்த்தில் ரூட்சை
வாதுசெய் வாதசூலை வளர்ந்திடும் கபம் இளைப்பு
நீதமாம் அசதி பித்தம் சோகையும் பாண்டு பீலி
பேதமாம் வாய்வு நோய்கள் பெயரும் இஞ்சி தன்னால் என்றே.

(பொருட்பண்பு நூல்)

Medicinal uses:

- It cures cold, cough, headache,asthma,kabha diseases, dyspepsia and digestion.
- The ethanol extract of rhizome of ginger produced significantly inhibition of the carrageenan-induced rat paw edema and a reduction in the number of writhing induced by acetic-acid in mice. It posses anti inflammatory and analgesic activity.

- Ginger has been found to suppress prostaglandin synthesis through inhibition of cyclo-oxigenase 1 and 2.
- Ginger also possess immune modulatory effects and is an effective antiviral and antibacterial activity.

VELLULI

Botanical name : Allium *sativum*.Linn

Sanskrit name : Lesuna

English name : Garlic

Tamil name : poondu

Other names : Lasunam, Kaayam, Ulli, Vellaipoondu, velvengayam.

Family : Lilliaceae

Parts used : Rhizome

Actions : Expectorant, Anthelmintic, Carminative, Tonic, Hepatoprotective, Anti diabetic, Anti tubercular, Anti bacterial, Anti atherosclerotic, Hypocholestremic, Anti carcinogenic.

Taste :Pungent

Potency :Hot

Division :Pungent

Phytochemicals: Diallyl mono,di,tri, tetra,penta,hexa,hepta sulfides.Vinylthiins and ajoenes.

GENERAL CHARACTER:

சன்னியொடு வாதந் தலைநோவு தாள்வலி
மன்னிவரு **நீர்கோவை** வன்சீதம்_அன்னமே
உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம்
வெள்ளுள்ளி தன்னால் வெருண்டு.

(அகத்தியர் குணவாகடம்)

உரையென வெள்ளைபூண்டு உறுதலைவலி வாய்பூட்டு
நிரையென வாதம் சீதம் நின்ற **நீர்கோவை** சன்னி
விரையில் ஆந்திரமும் குன்மம் வெகு கபம் குறுகுறுப்பு
தரையினில் கெற்பத்தோர்க்கும் தகுக்கமுண்டாமென்றே,

(பொருட்பண்பு நூல்)

Medicinal uses:

- Is the remedy for sanni,vatha diseases, headache, tetanus, rhinitis,chillness and haemoroids.
- Allinin were found to possess hepato-protective activity.
- Histopathological studies indicated retardative effect of garlic supplementation to cholesterol rich diet , on the development of atherosclerosis in rabbits.
- In goats garlic showed hypocholestremic and anti atherosclerotic effects.

`MURUNGAI VAER

Botanical name	:	Morringa *oleifera*,Lam.
Sanskrit name	:	Sigru-valkalum
English name	:	Horse radish,Drum stick tree.
Tamil name	:	Murungai
Other names	:	Sikuru,kiranjam,kizhavee,sobanjanam.
Family	:	Moringaceae
Parts used	:	Root
Actions	:	Anti lithic,anti septic,carminative,anti spasmodic,anti viral,anti inflammatory,anti bacterial, cardiac stimulant.
Taste	:	Bitter, Astringent, Sweet.
Potency	:	Coolent
Division	:	Sweet,pungent

GENERAL CHARACTER:

முருங்கைவேர்ப் பட்டைக்கு மூடு கபத்தோ
டொருஞ்குறாச் சன்னிசுரம் ஓடும்-அருங்கனக,
வட்டைப் பொருமுலையாய்! வாய்வொடுவி டங்களுமேற்
பட்டைக்குப் போமே பறந்து. - (அகத்தியர் குணவாகடம்)

Medicinal uses:

- All parts of the tree used in the treatment of ascites, rheumatism, venomous bites and as cardiac and circulatory stimulants.

KODIVELI

Botanical name	:	Plumbago *indica*,Linn.
Other names	:	Chitira moolam, kodi vanni,akni,vasagam.
Family	:	Plumbaginaceae
Parts used	:	Root
Actions	:	Anti septic,Anti pyretic,Anti bacterial,Anti oxidant.
Taste	:	Pungent
Potency	:	Hot
Division	:	Pungent

GENERAL CHARACTER:

கட்டி விரணங்கிரந்தி கால்கள் அரையாப்புக்
கட்டிச்சூலை வீக்கங் காழ்மூலம்-முட்டிரத்தக்
கட்டு**நீ ரேற்றங்** கனத்த பெருவயிறும்
அட்டுங் கொடிவேலி யாம்.

(அகத்தியர் குணவாகடம்)

Medicinal uses:

- It cures skin diseases, edema,piles, dyspepsia and ascites.
- Plumbagin is a crystallinesubstance present in plumbago *zeylanica.*
- Plumbagin showed regression of experimental tumor. Antimitotic,antifungal and antibacterial activities of plumbagin were reported.
- The methanol extract of root of plumbagin are effective against acute inflammation.
- Plumbagin possess anti inflammatory,cyto-toxic and anti-allergic effects.

OMAM

Botanical name	:	Carum copticum Benth & Hook.
Other names	:	Asamotham, thipiyam
Family	:	Apiaceae
Parts used	:	Seeds

Actions	:	Anti septic, Anti spasmodic, Carminative.
Taste	:	Pungent
Potency	:	Hot
Division	:	Pungent

GENERAL CHARACTER:

சீதசுரங் காசஞ் செரியாமந் தம்பொருமல்
பேதியிரைச் சல்கடுப்பு பேராமம்-ஓதிருமல்
பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ?
சொல்லொடுபோம் ஓமமெனச் சொல்.

(அகத்தியர் குணவாகடம்)

Medicinal uses:

C.copticum extracts and essential oil are reported to have anti cholinergic effect, anti spasmodic, bronchodilator, anti-tussive, anxiolytic, analgesic, anti inflammatory, anti microbial, anti viral, anti oxidant properties.

INDHUPPU

Sodium chloride impura (Rock salt)
Other names: Sainthavam, Sindhooram, Mathi koormai, Mathiuppu

GENERAL CHARACTER:

அஷ்டகுன்மம் மந்தம் அசுர்க்கரச்சூர் சீதபித்தந்
துட்ட இயம் நாடிப்புண் தோஷங்கண்-கெட்டமலங்
கட்டுவிட விந்துப்பைங் காமியநோய் வன்கரப்பான்
விட்டுவிட விந்துப்பை வின்

Medicinal uses:

- It is beneficial to treat 8 types of gunmam, indigestion,menorrhagia,chillness of the body,pitha&kapha diseases,constipation, sexually transmitted diseases and eczema.

CHUKKU

Botanical name	:	Zingiber *officinale*.Rosc.
Sanskrit name	:	Nagaram
English name	:	Dried ginger.
Tamil name	:	Chukku
Other names	:	Arukan,athagam,ubakullam,vidamoodiya amirtham.
Family	:	Zingiberaceae
Parts used	:	Rhizome
Actions	:	Carminative, Stimulant, stomachic.
Taste	:	Pungent
Potency	:	Hot
Division	:	Pungent

GENERAL CHARACTER:

விரும்பிடும் சூலை மந்தம் விடும் அதிசாரம் பேதி
இருமல் நெஞ்செரிப்பு மூலம் வாத **நீர்தோஷம்** குன்மம்
அரும்பிய பாண்டு தலைநோய் அருகிடும் என்று சொல்லு
அருகு தொக்கசதி சுக்கால் அகன்றிடும் என்றவாறே.

(பொருட்பண்பு நூல்)

சூலை மந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை
மூலம் இரைப்பிருமல் **மூக்குநீர்**-வாலகப
தோடமதி சாரந் தொடர்வாத குன்மநீர்த்
தோடம் ஆமம் போக்குஞ் சுக்கு.

(அகத்தியர் குணவாகடம்)

Medicinal uses:

Dried ginger is used to cure throbbing pain, indigestion,heart burning,derangement of three humours,haemorroids,wheezing,nasal discharge. It controls kapha and maintance body heat. Pain in the ear,buccal cavity&head,pain in the viscera,lacrimation,bacillary dyscentry various types of ageusia, anorexia, contamination of blood with dropsy, pricking pain in the abdomen,fever with cold,shivering.

MILAGU

Botanical name	:	Piper *nigrum* Linn.
Sanskrit name	:	Maricha
English name	:	Black pepper
Tamil name	:	Milagu
Other names	:	Kari, kaayam, kolagam, thirangal,malaiyali
Family	:	Piperaceae.
Parts used	:	Dried unripe fruit.
Actions	:	Acrid, carminative, Antiperiodic, stimulant, antidote.
Taste	:	Acrid, pungent
Potency	:	Hot
Division	:	Pungent

GENERTAL CHARACTER:

சீதசுரம் பாண்டு சிலேத்மங் கிராணிகுன்மம்
வாதம் அருசிபித்தம் மாமூலம்-ஓதுசன்னி
யாசமபஸ் மாரம் அடன்மேகம் காசமிவை
நாசங் கறிமிளகினால்.

(அகத்தியர் குணவாகடம்)

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

Medicinal uses:

- It is used in fever,piles, gastric ailments,asthma, anemia and sore throat.
- Piperine has anti inflammatory activity against carrageenin-induced rat paw oedema, cotton pellet granuloma and croton oil induced granuloma pouch in animal modal. Piperine possess cyclooxygenase inhibitory activity.
- Piper nigrum extract significantly increased the analgesic activity of diclofenacsodium and pentazocine.
- The polysaccharide fractions of piper nigrum acts as immune enhancer.
- Piperine possess anti allergic activity.

THIPPILI

Botanical name	:	Piper *longum* Linn
Sanskrit name	:	Pippali
English name	:	Long pepper
Tamil name	:	Thippili
Other names	:	Aarkathi, kolagam, ambu, aathi marunthu
Family	:	Piperaceae
Part used	:	Dried unripe fruits.
Actions	:	Stimulant, carminative
Taste	:	Pungent
Potency	:	Hot
Division	:	Sweet

GENERTAL CHARACTER:

கண்டிடயிருமல் குன்மம் கபமொடு யீளை பாண்டு
மண்டிட பீலி அரோசியம் **தலைநோய்** வாதம்
ஒண்டிய சுரமுத்தோஷம் குளிரொடு வலியும் மாறும்
தண்டிய தாதுண்டாகுத் திப்பிலி குணமிதாமே - (பொருட்பண்பு நூல்)
ஆசனநோய் தொண்டைநோய் ஆவரண பித்தமுதல்
நாசிவிழி காதிவைநோய் நாட்புழுநோய்-வீசிடுவி
யங்கலாஞ்ச னஞ்சிதையும் அம்பாய் அழிவிந்தும்
பொங்கலாஞ்ச நங்கையர்கோட்போல் - (தேரன் குணவாகடம்)

Medicinal uses

- It relieves cold,cough,asthma,hoarseness,diseases of nose,eye and ear.
- Piper longum posses anti-inflammatory,anti-bacterial and immune-stimulatory activity.

PERUNGAYAM

Botanical name	:	Ferula *asafoetida*
Sanskrit name	:	Hingu
English name	:	Asafoetida
Tamil name	:	Perungayam
Other names	:	Athiyakiragam, hingu, kayam, santhunasam.
Family	:	Apiaceae
Part used	:	Gum resin
Actions	:	Antispasmodic, expectorant, laxative, carminative, anthelmintic.
Taste	:	Bitter
Potency	:	Hot
Division	:	Pungent

GENERTAL CHARACTER:

சொல்லிடும் விஷம் கிருமி மகோதரம் குன்மம் சேற்பனம்
வெல்லிடும் பல்நோய் மந்தம் வாதமும் நெஞ்சுள் நோவு
அல்லிடும் அலகில் நோவும் அகன்றிடும் கெற்பச் சூலை
கல்லிடும் பெருங்காயத்தால் கெற்பவாய் வெல்லாம் போலே.

(பொருட்பண்பு நூல்)

Medicinal uses:

Asafoetida is used for the cure of asthma,diarrhea,skin diseases and .

- Extracts of asafoetida are used as an antispasmodic,diuretic, vermifuge and an anti allergic.
- Asafoetida possess anti-mutagenic and anti-cancer properties.

SEVIYAM

Botanical name	:	Piper nigrum
Sanskrit name	:	Maricha
English name	:	Black pepper root
Tamil name	:	Milagin vaer
Other names	:	Kandeerai,saviyam,savikai
Family	:	Piperaceae.
Part uses	:	Root
Actions	:	Carminative, anti-periodic
Taste	:	Acrid,pungent
Potency	:	Hot
Division	:	Pungent

GENERTAL CHARACTER:

சூலை அருகிசன்னி தொல்லிருமல் ஈளைபித்தம்
மேலைக் **குரற்கம்மல்** வெங்களநோய்-மூலசுரம்
கவ்வியங்கத் தேறு கனதா வரவிடமுஞ்
செவ்வியங் கொள்ளவிடுந் தேர். - (அகத்தியர் குணவாகடம்)

Medicinal uses

- It is used in fever,piles, gastric ailments,asthma, anemia and sore throat.
- Piperine has anti inflammatory activity against carrageenin-induced rat paw oedema, cotton pellet granuloma and croton oil induced granuloma pouch in animal modal. Piperine possess cyclooxygenase inhibitory activity.
- Piper nigrum extract significantly increased the analgesic activity of diclofenacsodium and pentazocine.
- The polysaccharide fractions of piper nigrum acts as immune enhancer.
- Piperine possess anti allergic activity.

NAVACHARAM

Scientific name	:	Ammonium chloridum
Tamil name	:	Navacharam
Other names	:	Ishtigai,saligai,suligai,padu.
Actions	:	Expectorant, Diuretic
Taste	:	Sour and bitter.

GENERTAL CHARACTER:

என்றிடும் குடலுச்சூலை இடமகோதரமும் குன்மம்
வென்ற கல்லடைப்பு வாதம் **பீனிசம் மண்டைநோவு**
துன்னிய சன்னி மூர்ச்சை திரிதோஷம் **மூக்கடைப்பு**
நன்று கற்றாளை நாற்றம் நவாச்சாரம் கொள்ளப்போமே.-(பொருட்பண்பு நூல்)
குன்மங் குடற்சூலை சொல்லும் மகோதரத்தை
வன்மையுறுங் கல்லடைப்பை மாற்றுங்காண்-கன்மக்
கவிச்சுமுத் தோஷங் கனவாதம் நீக்கும்
நவாச்சாரம் மாதே நவில்.- (அகத்தியர் குணவாகடம்)

Medicinal uses:

- Navacharam is the remedy for gunmam,throbbing pain,ascites,renal calculai.
- It also neutralizes three humours.

KARUNCHEERAGAM

SBotanical name	:	Nigella sativa.Linn
Sanskrit name	:	Upakunchika
English name	:	Black cumin, small fennel
Other names	:	Aranam, upakunjikai
Family	:	Rananunculacae
Part uses	:	Seeds
Actions	:	Carminative, diuretic, anthelmintic, parasticide.
Taste	:	Bitter
Potency	:	Hot
Division	:	Pungent

GENERAL CHARACTER:

கருஞ்சீரகத்தான் கரப்பனொடு புண்ணும்
வருஞ்சிராய்ப் **பீநசமு மாற்றும்**-அருந்தினால்
காய்ச்சல் **தலைவலியுங்** கண்வலியும் போமுலகில்
வாய்ச்ச மருந்தெனவே வை. - (அகத்தியர் குணவாகடம்)

GENERAL CHARACTER:

போதவே தாதுண்டாகும் பொருந்து **பீனிசம்**புண் காய்ச்சல்
நீதமாம் கரப்பான் **மண்டை நோவொடு கண்நோய்** மாறும்
சீதமும் வலிகள் விஷம் சிறப்புற ஓடிப்போகும்
மாதர்கள் சிசுவளரும் மதி கருஞ்சீரகத்தால். - (பொருட்பண்பு நூல்)

Medicinal uses:

- Black cumin used in the treatment of liver ailments, anaemia, ascites, piles, indigestion, spermatorrhoea and dropsy.
- Black cumin extracts was found to show Anti cancer activity.
- Alcoholic extracts of the seed oil showed antibacterial, broncho-dilatory, hypo-tensive and immune-stimulant activity.

PIRANDAI

Botanical name	:	Cissus *quadrangularis*.Linn
Sanskrit name	:	Asthisamhari
Tamil name	:	Pirandai
Other names	:	Vachiravalli
Family	:	Vitaceae
Part used	:	Tuber
Actions	:	Alterative, Emmenagogue, Stomachic.
Taste	:	Pungent
Potency	:	Hot
Division	:	Pungent

GENERAL CHARACTER:

பிரண்டையை நெய்யால்வறுத்துப் பின்னரைத்து மாதே
வெருண்டிடா தேற்று விழுங்கில்-அரண்டுவரும்
மூலத் தினவடங்கும் மூலவி ரத்தமறும்
ஞாலத்தி னுள்ளே நவில் - (அகத்தியர் குணவாகடம்)

Medicinal uses:

- The plant which has been proved to be highly effective in alleviating pain, reducing swelling and promoting healing of the simple fractures as well as associated disorders.

PASUNEI

GENERAL CHARACTER:

தாக முழலைகட்கஞ் சர்த்திபித்தம் வாயுபிர
மேகம் வயிற்றெரிவு விக்கலழல்-மாகாசங்
குன்மம் வறட்சி குடற்புரட்ட லஸ்திகட்கஞ்
சொன்மூலம் போக்குநிரைத் துப்பு. - (பதார்த்த குணசிந்தாமணி)

Medicinal uses:

Cow’s ghee cures dryness, vomiting,derangement of pitha and vatha, gonorrhea,gastritis,hiccup,body heat,chronic cough,gastric ulcer,dryness of the body, vomiting sensation fever due to bony origin,anorectal diseases and abnormal peristaltic movements.

PIRANDAI

VELLULLI

NAVACHARAM

KARUNGEERAGAM

KODIVELI

OMAM

MILAGU

MURUNGAI VER

INJI

INTHUPPU

SAMUTHRA PAZHAM

GHEE

CHUKKU

SEVIYAM

PERUNGAYAM

SAMUTHRA PAZHA NEI

RESULTS AND OBSERVATION

RESULTS AND OBSERVATION

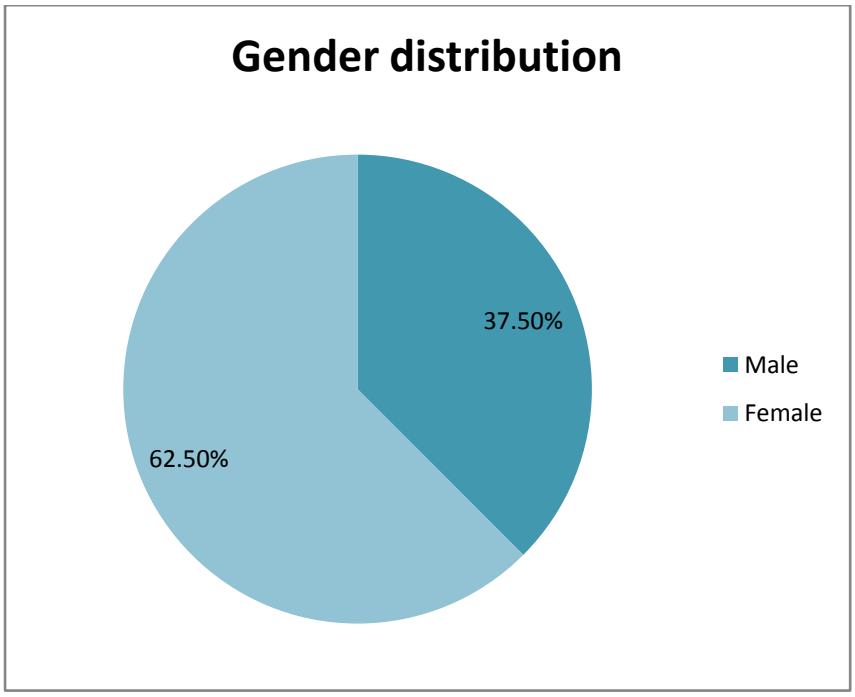
Results of the study were observed with respect to the following criteria;

1. Sex distribution
2. Age distribution
3. Occupation
4. Family history
5. Diet
6. Kaalam
7. Chronicity of illness
8. Gunam
9. Past history
10. Triggering factor
11. Thinai
12. Paruva kaalam
13. Gnanenthiriyam
14. Kosangal
15. Derangement of Vatham
16. Derangement of Pitham
17. Derangement of Kabam
18. Derangement of udal thathukal
19. Derangement of envagai thervugal
20. Neerkkuri anlysis
21. Neikkuri analysis
22. Clinical features distribution
23. Improvement after treatment

Gender distribution

Sl. No	Sex	No of Cases	Percentage
1	Male	15	37.5%
2	Female	25	62.5%

Figure 1



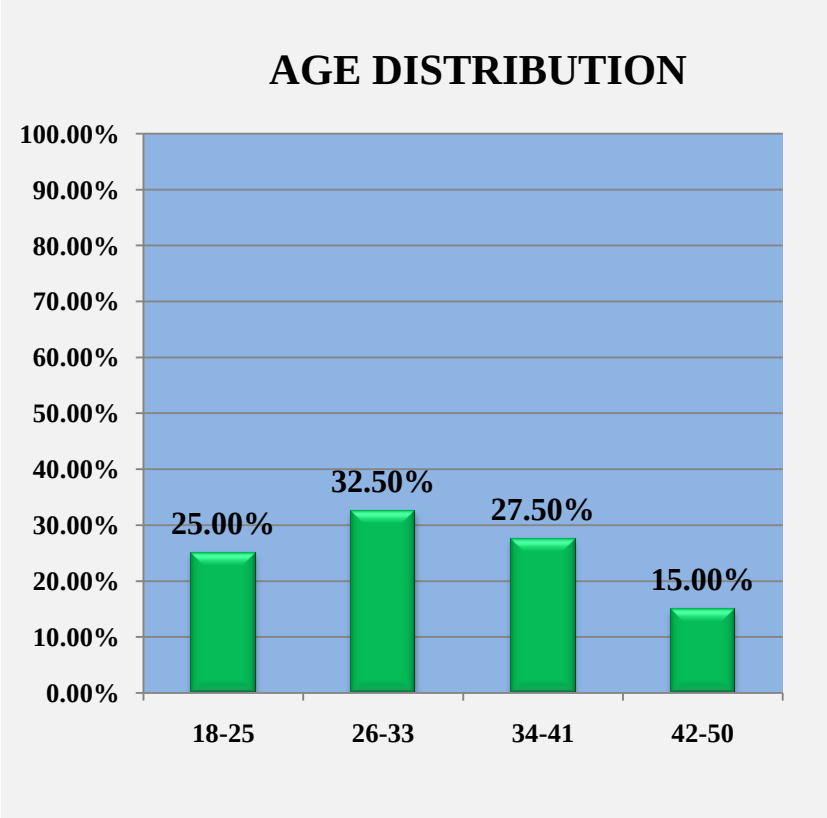
Inference:

Among 40 cases the prevalence of the disease was found to be higher in females (25 cases, 62.5%).

Age Distribution:

Sl. No	Age	No of Cases	Percentage
1	18-25	10	25%
2	26-33	13	32.5%
3	34-41	11	27.5%
4	42-50	6	15%

Fig No: 2



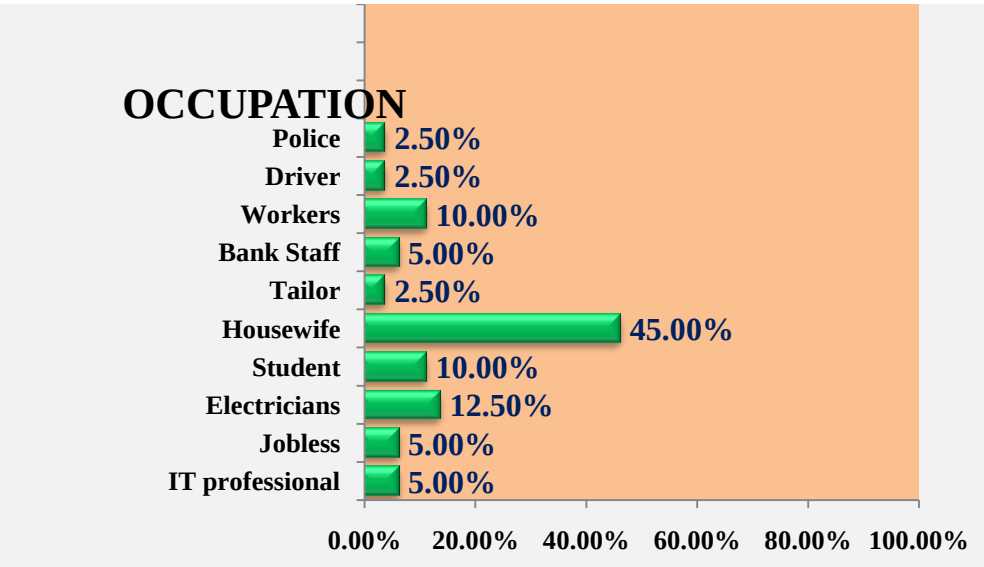
Inference:

Among 40 cases the prevalence of disease was found to be higher among the age group of 26-33 (13 cases, 32.5%). 27.5% of cases were belongs to 34-41, 25% of cases were belongs to 18-25and 15% of cases were belongs to 42-50 age group.

Occupation

Sl. No	Nature of Work	No. of Cases	Percentage
1	IT Profession	2	5%
2	Jobless	2	5%
3	Electricians	5	12.5%
4	Student	4	10%
5	Housewife	18	45%
6	Tailor	1	2.5%
7	Bank Staff	2	5%
8	Workers	4	10%
9	Driver	1	2.5%
10	Police	1	2.5

Fig No: 3



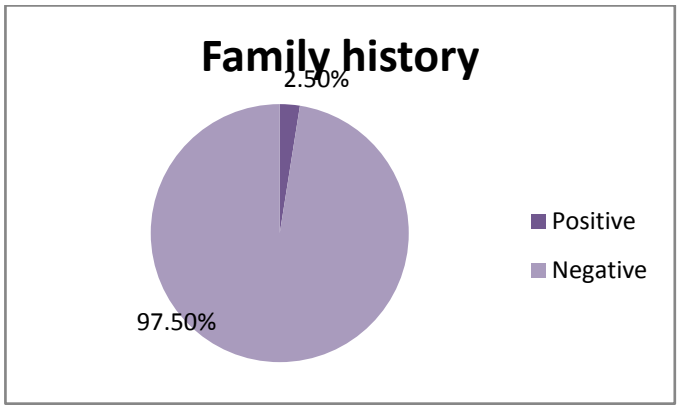
Inference:

Among 40 patients, (45%) 18 cases were house wives, 5 cases (12.5%) were electricians and 4 cases (10%) were students and workers, 5% were IT profession, bank staff and jobless, 2.5% were Police, driver and driver.

Family History:

Sl. No	Family history	No of Cases	Percentage
1	Family History (+ve)	1	2.5%
2	Family History (-ve)	39	97.5%

Figure 4



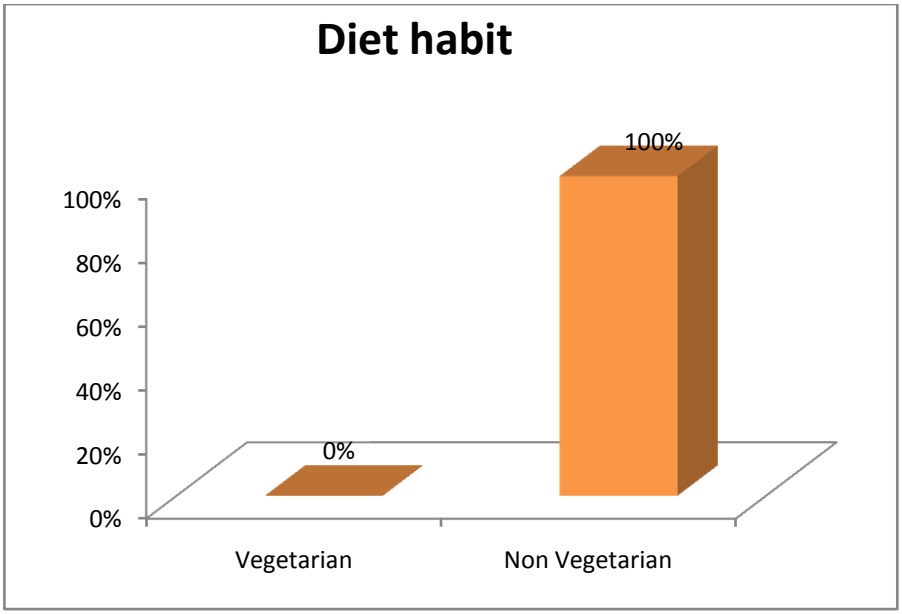
Inference:

Among 40 cases, 97.5% of patients do not have any family history. Only 2.5% of patients had family history.

Dietary Habits

Sl. No	Dietary Habits	No of Cases	Percentage
1	Vegetarian	0	0%
2	Non Vegetarian	40	100%

Fig No: 5



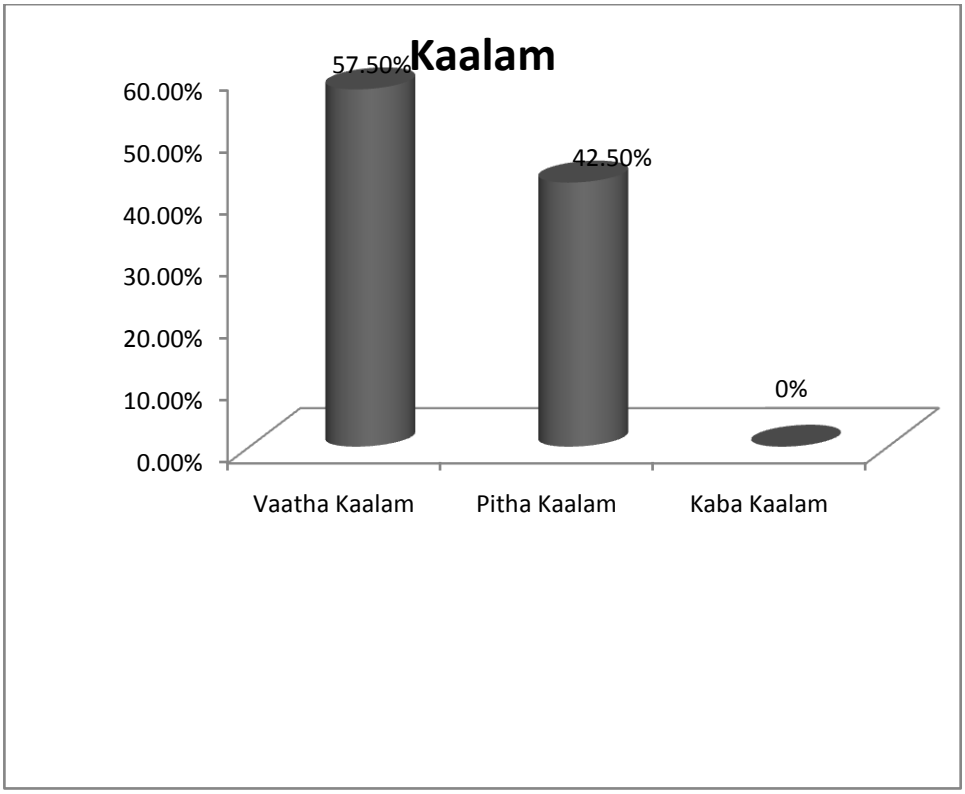
Inference:

Among the 40 cases, all of them were under Non-Vegetarian category.

Kaalam Distribution:

S.No	Kaalam	Percentage
1.	Vatha kaalam	57.5%
2.	Pitha kaalam	42.5%
3.	Kaba kaalam	0

Fig No: 6



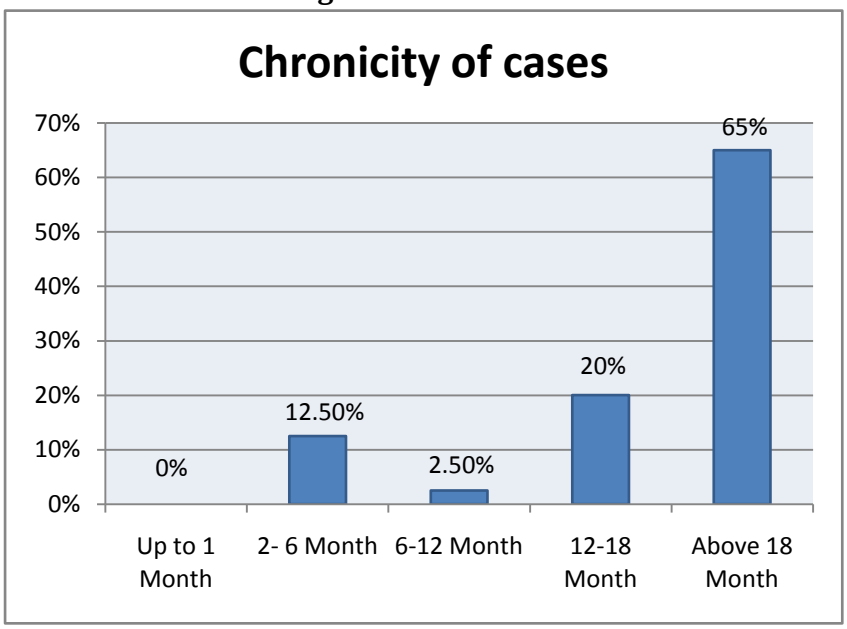
Inference:

Among 40 cases, 57.5% of patients were in vaatha kaalam (age up to 33 years). 42.5% of patients were in Pithakaalam (age up to 34-66 years).

Chronicity of illness:

Chronicity of illness	No. of Cases	Percentage
Up to 1 Month	0	0%
2- 6 Month	5	12.5%
6-12 Month	1	2.5%
12-18 Month	8	20%
Above 18 Month	26	65%
Total	40	100%

Fig No: 7



Inference:

Among 40 cases, 65% patients had 18 months chronicity of illness, 20% of patients had 12-18 months chronicity, 12.5% of cases had 2-6 months chronicity and 2.5% of patients had 6-12 months chronicity.

Gunam (Quality and Characters)

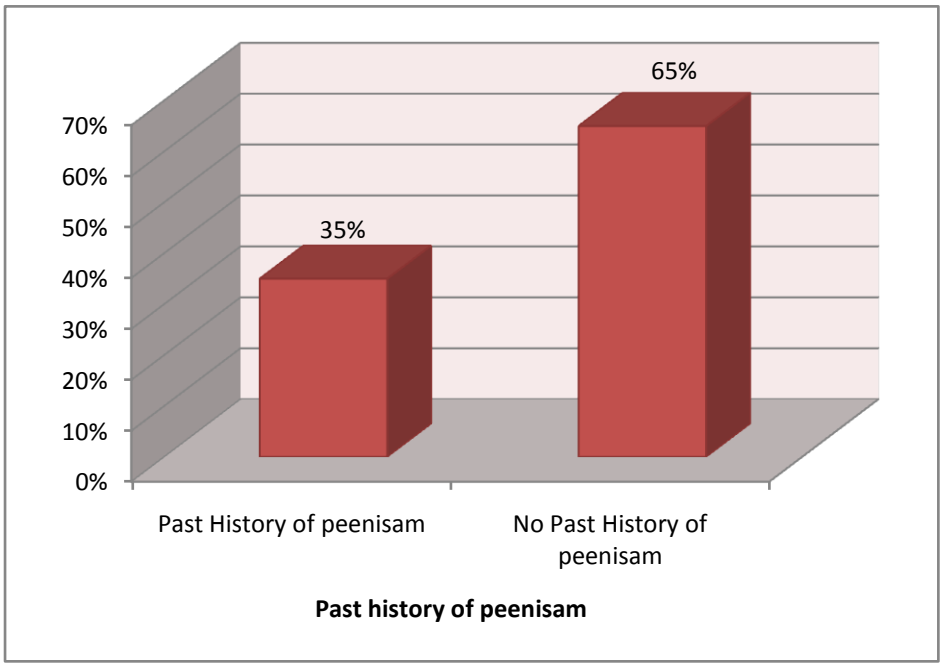
Sl. No	Gunam	No of Cases	Percentage
1	SathuvaGunam	0	0%
2	RajoGunam	40	100%
3	ThamoGunam	0	0%

Inference: Among 40 cases, all of them had Raso gunam

Past History of peenisam:

Sl. No	Past History	No of Cases	Percentage
1	Past History of peenisam	14	35%
2	No Past History of peenisam	26	65%

Fig No: 8



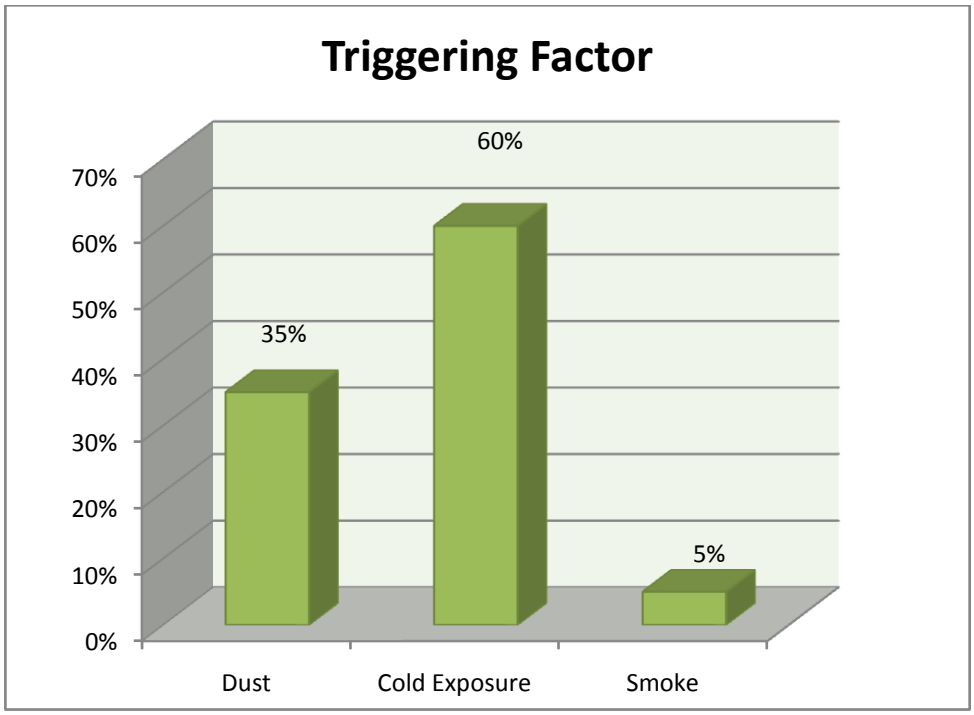
Inference:

Among 40 cases, 65% of patients don't have any past history. Only 35% of cases had past history of Peenisam**.**

Triggering Factor:

Sl. No	Triggering Factor	No. of Cases	Percentage
1	Dust	14	35%
2	ColdExposure	24	60%
3	Smoke	2	5%
4	Total	40	100%

Fig No: 9



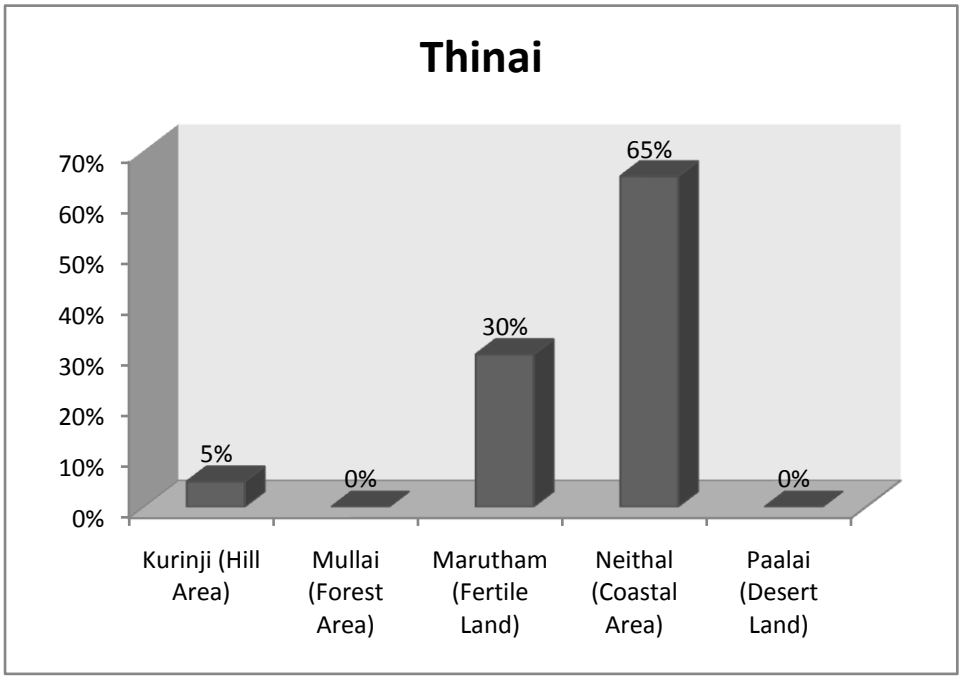
Inference:

Among 40 cases, 60% of patients had cold exposure, 35% of patients had dust, 5% of cases had smoke as triggering factors.

Thinai Reference:

Sl. No	Thinai	No. of Cases	Percentage
1	Kurinji (Hill Area)	2	5%
2	Mullai (Forest Area)	0	0%
3	Marutham (Fertile Land)	12	30%
4	Neithal (Coastal Area)	26	65%
5	Paalai (Desert Land)	0	0%

Fig No: 10



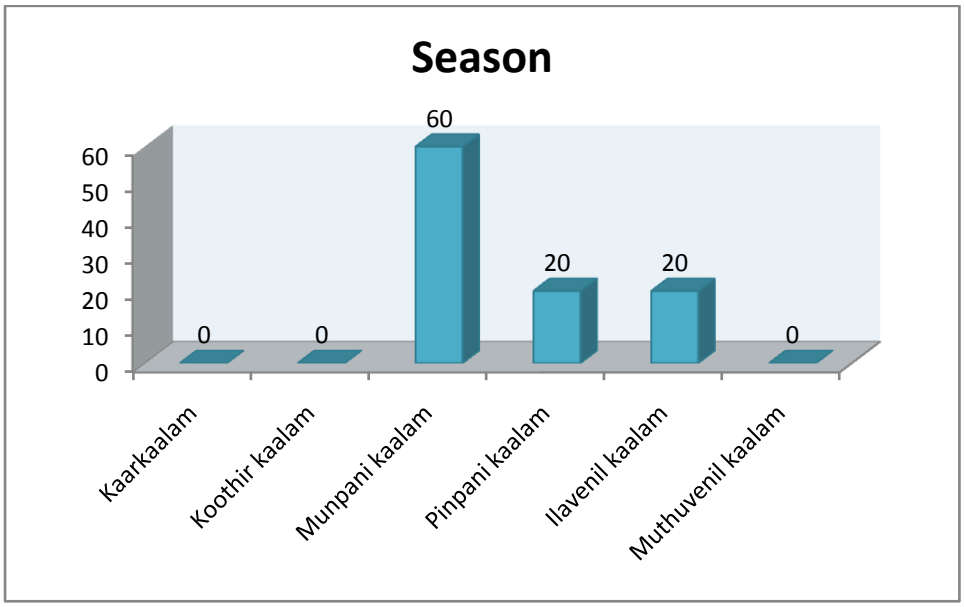
Inference:

Among 40 cases, 65% of cases were belongs to Neithal nilam, 30% of cases belongs to Marutha nilam, 5% of cases were belongs to Kurinji nilam.

Paruvakalaam

Season	No of cases	Percentage
1. Kaar kaalam	0	0
2. Koothir kaalam	0	0
3. Munpani kaalam	24	60
4. Pinpani kaalam	8	20
5. Ilavenil kaalam	8	20
6. Muthuvenil kaalam	0	0

Fig No: 11



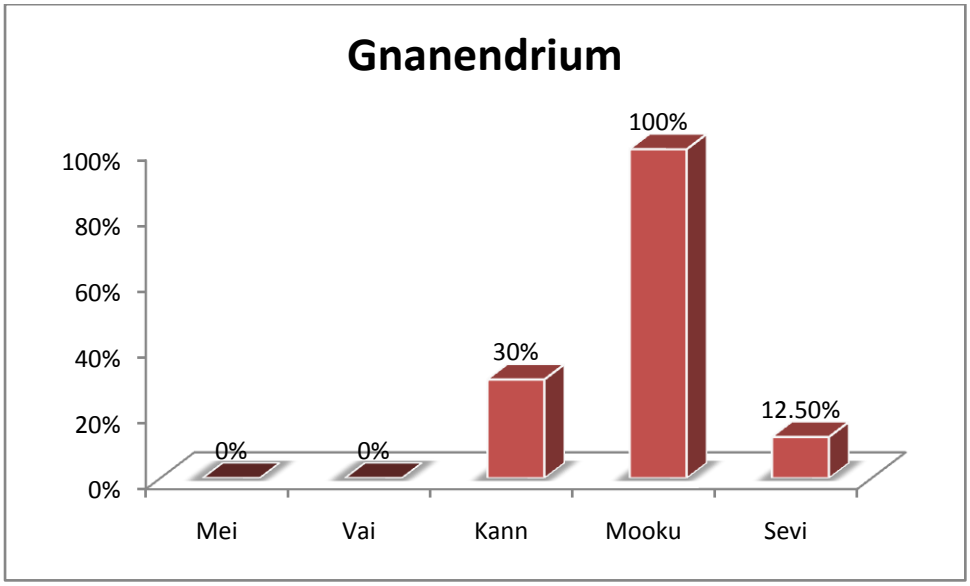
Inference:

Among 40 cases, 60% of patients were suffered in Munpanikaalam, 20% of patients were suffered in Pinpani kaalam and another 20% of cases were suffered in ilavvenil kaalam

Gnanendrium:

Sl. No	Gnanendrium	No of Cases	Percentage
1.	Mei	0	0%
2.	Vai	0	0%
3.	Kann	12	30%
4.	Mooku	40	100%
5.	Sevi	5	12.5%

Fig No-12



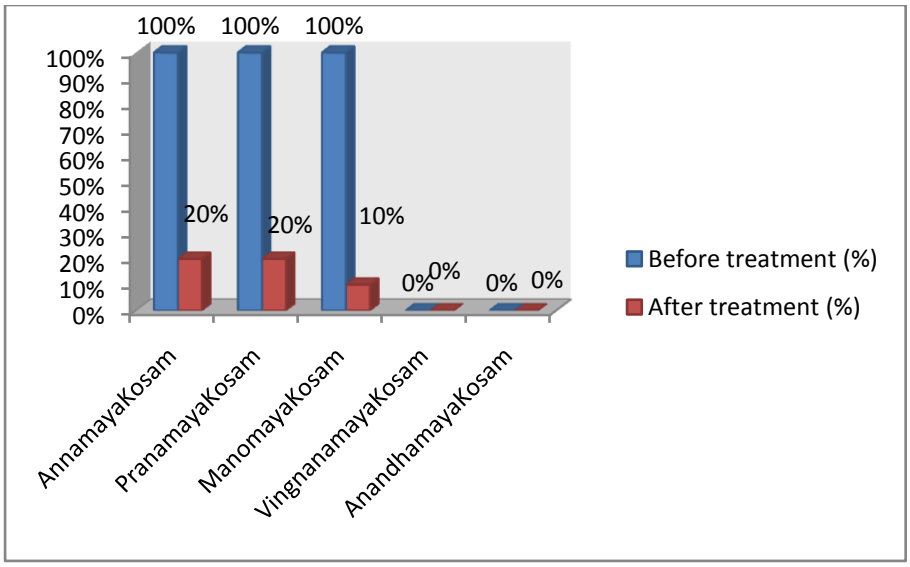
Inference:

Among 40 cases, all the patients had Nasal obstruction, temporary anosmia. 30% of patients had Dullness of both eyes, 12.5% of patients had Ear obstruction.

Kosangal:

Sl. No	Kosangal	Before treatment (%)	After treatment (%)
1.	AnnamayaKosam	100%	20%
2.	PranamayaKosam	100%	20%
3.	ManomayaKosam	100%	10%
4.	VingnanamayaKosam	0%	0%
5.	AnandhamayaKosam	0%	0%

Fig No-13



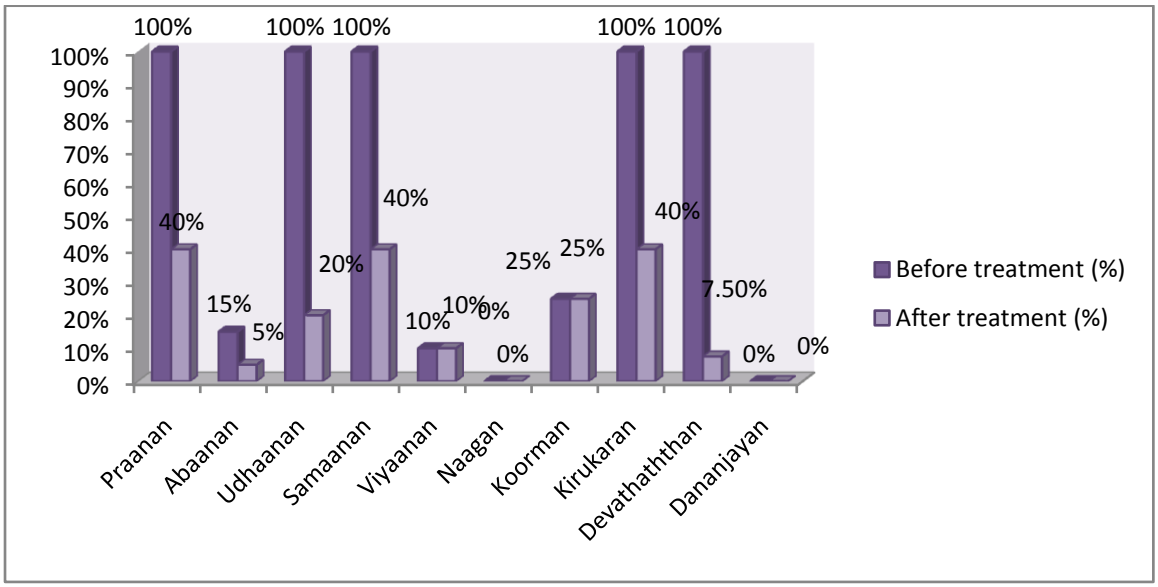
Inference:

Among 40 cases, all of them were affected with Annamayakosam, Piranamaya kosam, and Manomaya kosam in before treatment. After treatment 20% of patients were affected with Annamaya kosam and piranamayakosam, and 10% of cases were affected with manomayakosam.

Vaatham

Sl. No	Classification of Vaatham	Before treatment (%)	After treatment (%)
1	Praanan	100%	40%
2	Abaanan	15%	5%
3	Udhaanan	100%	20%
4	Samaanan	100%	40%
5	Viyaanan	10%	10%
6	Naagan	0%	0%
7	Koorman	25%	25%
8	Kirukaran	100%	40%
9	Devathaththan	100%	7.5%
10	Dananjayan	0%	0%

Fig No-14



Inference:

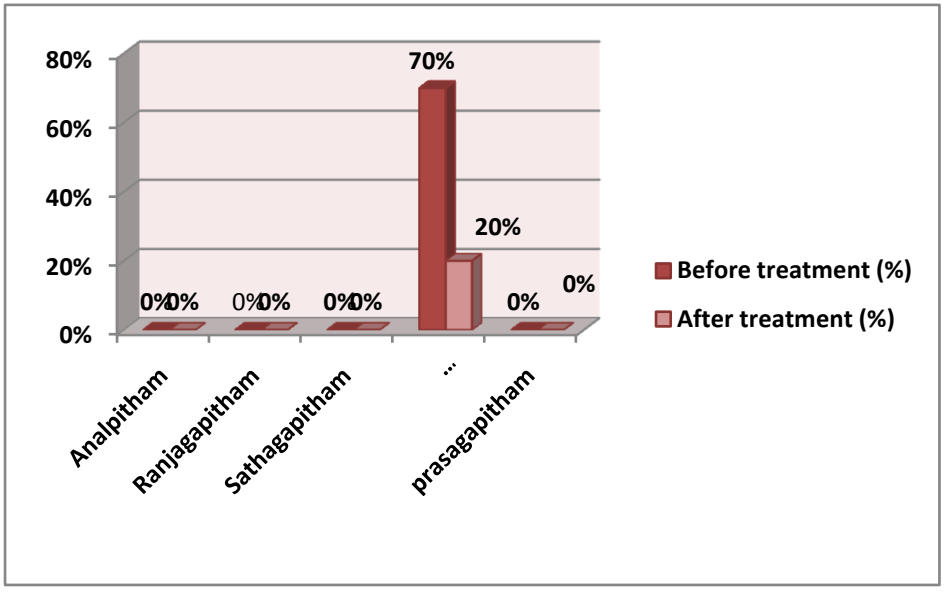
Among 40 cases, before treatment all of them were affected with Piranan, Udhanan, Smaanan, Kirukaran and Devathathan, 15% of cases were affected with Abaanan, 10% of cases were affected with Viyanan, 25% of cases were affected with Koorman.

After treatment, 40% of cases were affected with Piranan, Samaanan and Kirukaran, 20% of cases were affected with Udhanan, and 7.5% of cases were affected with Devathathan.

Piththam

Sl. No	Classification of Pitham	Before treatment (%)	After treatment (%)
1	Analpitham	0%	0%
2	Ranjagapitham	0%	0%
3	Sathagapitham	0%	0%
4	Aalosagapitham	70%	20%
5	prasagapitham	0%	0%

Fig No: 15



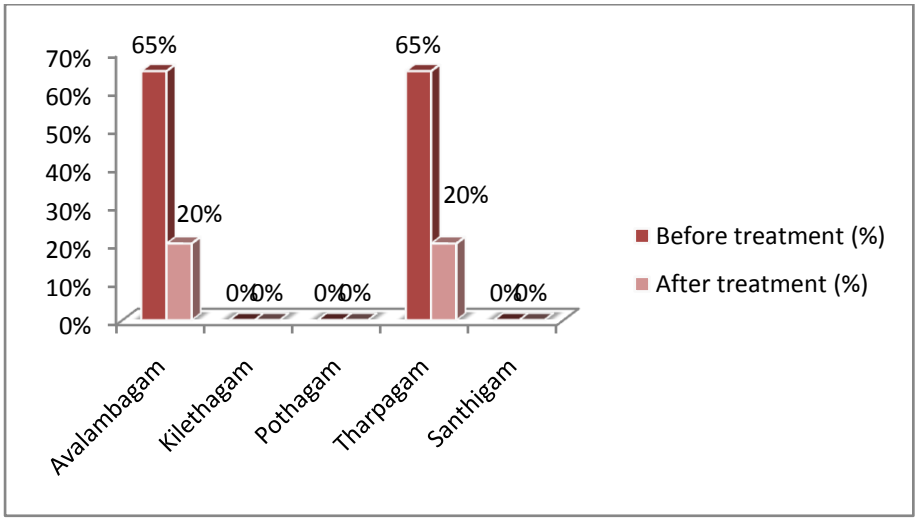
Inference:

Among 40 cases, 70% of patients were affected with Aalosaga pitham in before treatment. After treatment, only 20% of patients were affected with Aalosagaptham.

Kabam

Sl. No	Classification of Kabam	Before treatment (%)	After treatment (%)
1	Avalambagam	65%	20%
2	Kilethagam	0%	0%
3	Pothagam	0%	0%
4	Tharpagam	65%	20%
5	Santhigam	0%	0%

Fig No: 16



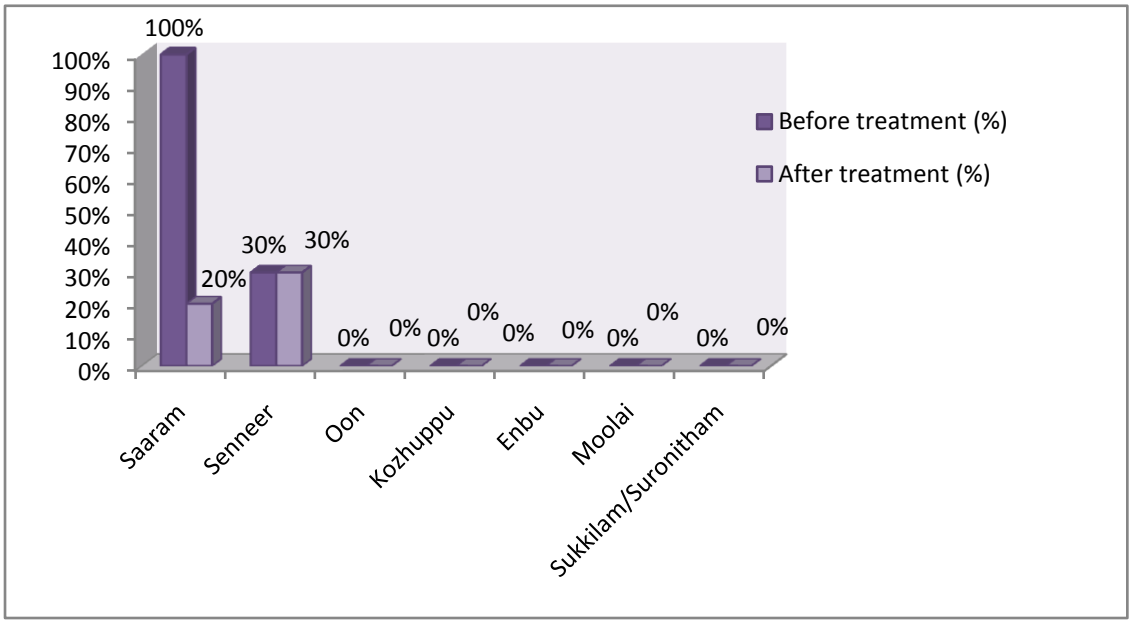
Inference:

Among 40 cases, 65% of patients were affected with Avalambagam and Tharpagam in before treatment. After treatment it was affected in only 20% of patients.

UdalKattukkal

Sl. No	UdarKattukkl	Before treatment (%)	After treatment (%)
1	Saaram	100%	20%
2	Senneer	30%	30%
3	Oon	0%	0%
4	Kozhuppu	0%	0%
5	Enbu	0%	0%
6	Moolai	0%	0%
7	Sukkilam/Suronitham	0%	0%

Fig No: 17



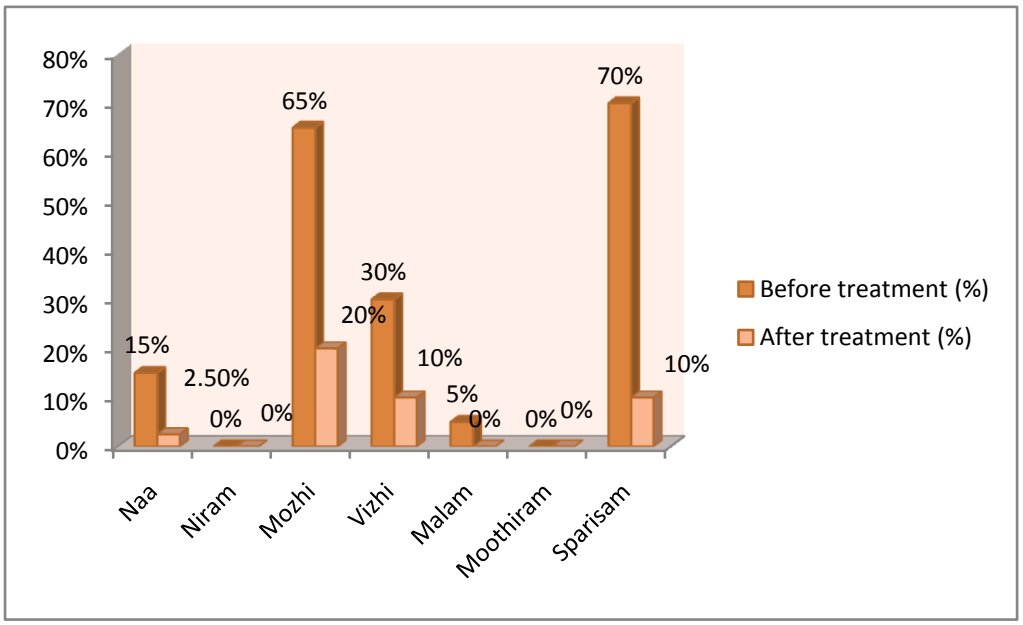
Inference:

Among 40 cases, 100% of patients were affected with Saaram, 30% of patients were affected with Senneer in before treatment. After treatment 20% of patients were affected with Saaram.

EnvagaiThervu

1	Envagaithervu	Before treatment (%)	After treatment (%)
2	Naa	15%	2.5%
3	Niram	0%	0%
4	Mozhi	65%	20%
5	Vizhi	30%	10%
6	Malam	5%	0%
7	Moothiram	0%	0%
8	Sparisam	70%	10%

Fig No: 18



Inference:

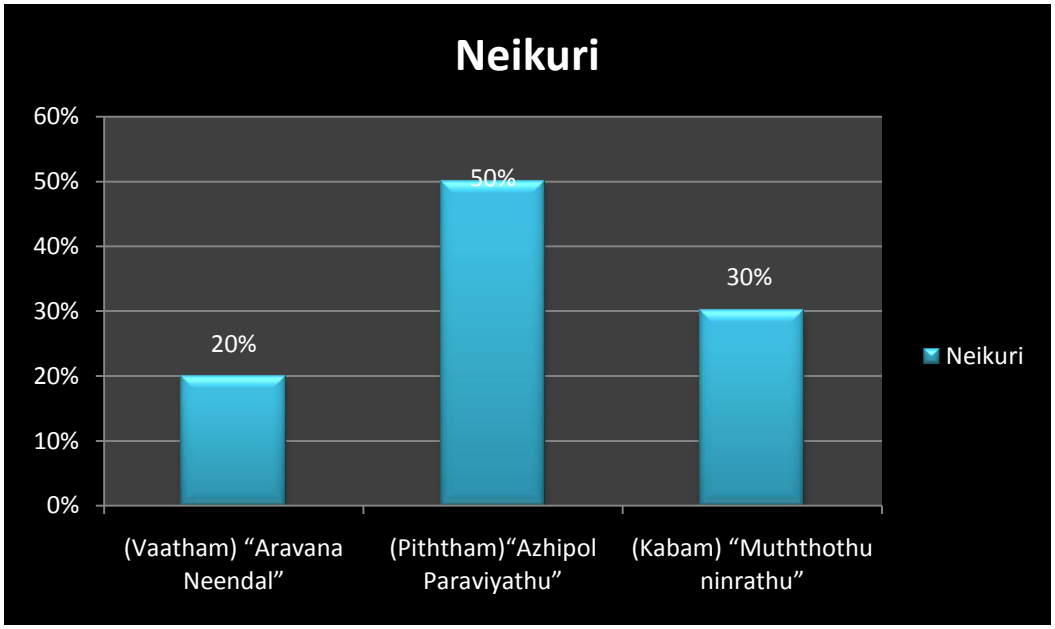
Among 40 cases, 70% of patients were affected with Sparisam, 65% of patients were affected with Mozhi, 30% were affected with Vizhi, 15% were affected with Naaand 5% were affected with Malam in before treatment.

After treatment 10% of patients were affected with Sparisam and Vizhi, 20% were affected with Mozhi and 2.5% were affected with Naa.

Neerkkuri, Neikkuri:

Sl. No	Type of Test	No. of Cases	Percentage
1	**Neerkkuri**:		
	" Niram" - Pale yellow -Dark yellow	24 16	60% 40%
2	**Neikkuri**:		
	(Vaatham) "AravanaNeendal"	8	20%
	(Piththam)"AzhipolParaviyathu"	20	50%
	(Kabam) "Muththothuninrathu"	12	30%
	Others	0	0%

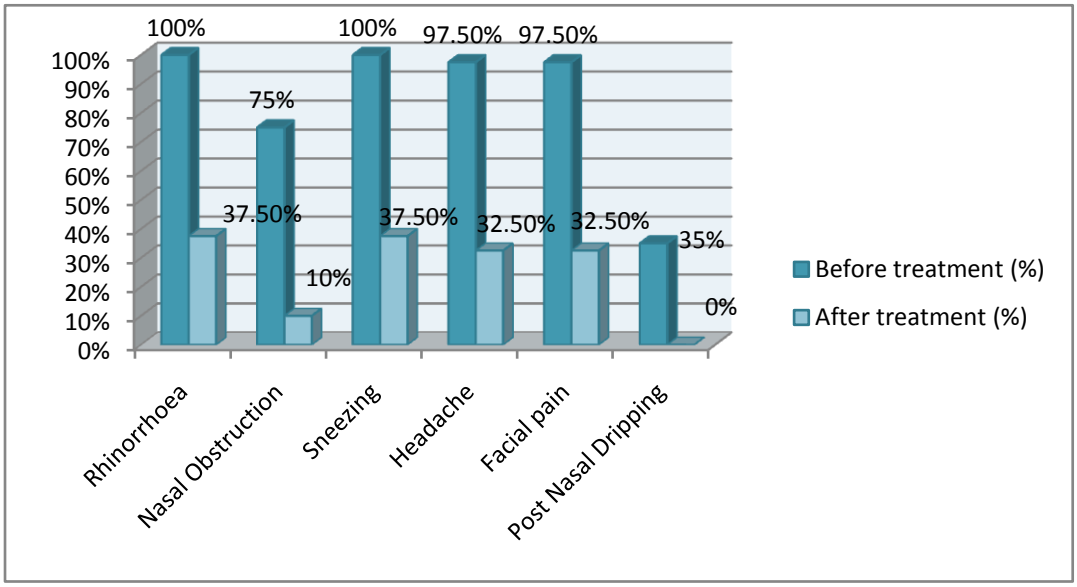
Fig No: 19



Clinical Features

S.No	Clinical Features	Before treatment (%)	After treatment (%)
1	Rhinorrhoea	100%	37.5%
2	Nasal Obstruction	75%	10%
3	Sneezing	100%	37.5%
4	Headache	97.5%%	32.5%
5	Facial pain	97.5%	32.5%
6	Post Nasal Dripping	35%	0%

Fig No: 20



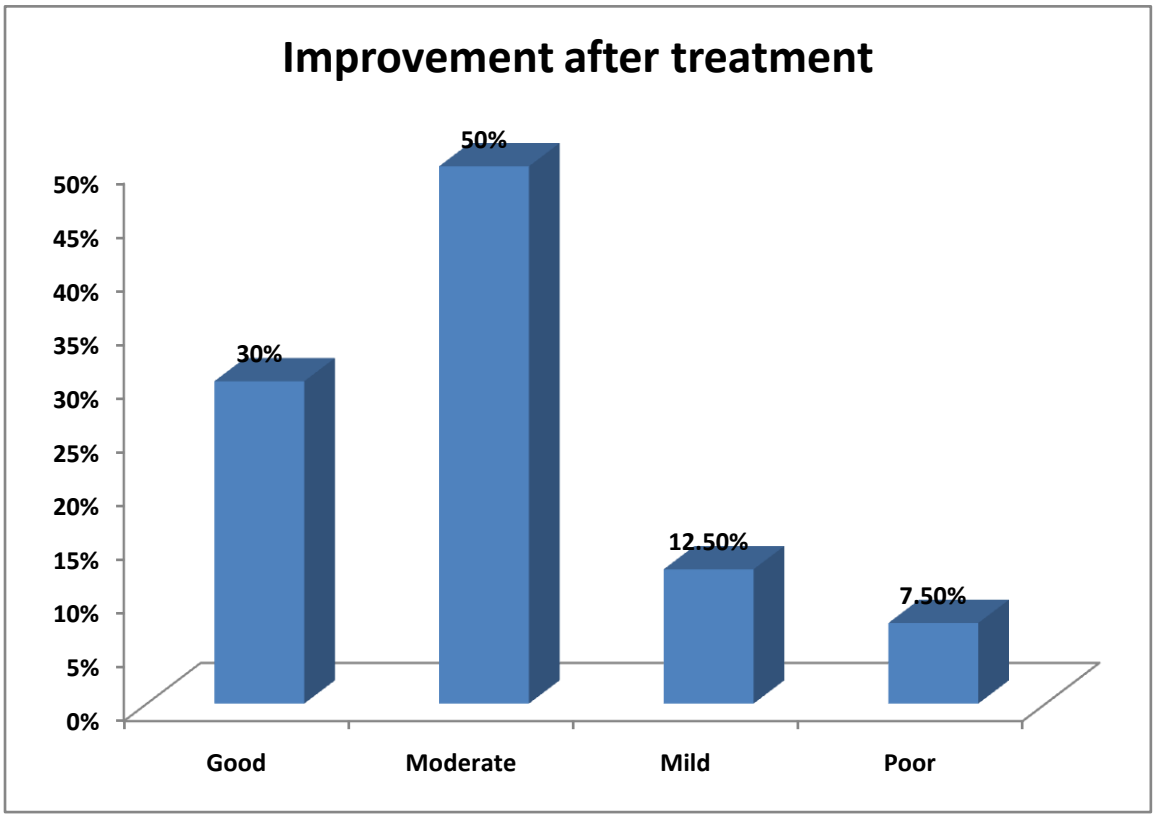
Inference:

Among 40 cases, 100% of patients had Rhinorrhoea and sneezing, 97.5% had Head ache and facial pain 75% of patients had Nasal obstruction, 35% of patients had Post nasal dripping in before treatment.

After treatment, 37.5% of patients had Rhinorrhoea and sneezing, 32.5% had head ache and facial pain and 10% had Nasal obstruction.

RESULT:

Improvement after treatment	GOOD	MODERATE	MILD	POOR
	30%	50%	12.5%	7.5%



Inference:

Among 40 cases, 30% of patients showed Good improvement, 50% showed Moderate improvement, 12.5% showed Mild improvement and 7.5% showed Poor improvement.

BLOOD INVESTIGATION (Haematology)

S. NO	OP NO	NAME	A/S	TC Cells/cumm		DC (%)							
						P	P	L	L	M	M	E	E
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	I57950	Arun joshi.S	30/m	8400	9000	62	60	32	31	-	-	6	8
2	I22078	Anitha.P	26/f	7600	8000	65	60	32	34	-	-	3	6
3	I47497	Muruga selvi.	24/f	7300	8200	54	52	41	40	5	0	-	-
4	G97302	Swarnalakshmi	21/f	8000	7900	60	60	34	36	6	4	-	-
5	I41877	Sinduja.S	27/f	6900	8200	63	64	33	32	-	-	4	4
6	I45501	Ellammal	41/f	8000	8400	55	54	37	38	3	5	-	-
7	I47469	Sarala.M	27/f	8300	7200	63	60	33	30	-	-	4	8
8	I39449	Jayanthi.s	40/f	10900	11300	56	55	38	41	2	4	4	-
9	H46122	Lakshmisudha	36/f	5300	5600	46	50	47	40	0	0	7	10
10	I46919	Vimalkumar.N	36/m	6000	6000	54	55	38	39	0	0	8	6
11	I46798	Kavitha,S	28/f	7100	7400	52	50	40	38	0	0	8	10
12	I42082	Kavitha.T	31/f	6200	7000	54	56	40	37	0	0	6	7
13	I43334	Nanthini.N	24/f	7900	6400	48	51	48	44	0	0	4	5
14	I44446	Parameshwari	33/f	8300	7900	69	68	25	25	1	0	5	7
15	I38041	Manivannan.E	41/m	8400	6900	62	63	31	32	0	0	7	5
16	I30933	Meena.R	27/f	8500	7200	60	62	30	30	0	0	9	5
17	I39306	Hemavathy.N	41/f	8100	7200	59	56	37	41	-	-	-	-
18	I19082	Mahendran	30/m	8700	8400	61	65	34	29	5	6	-	-
19	H99884	Ganesh Shankar	24/m	10900	5100	78	53	18	41	-	-	4	6
20	I41510	Saroja.S	45/f	7600	7600	62	61	29	31	-	-	9	8
21	H77505	Thilagavathy.N	25/f	5700	5400	70	60	22	33	-	-	8	7
22	H95096	Parthiban.G	41/m	8000	8100	50	50	41	43	9	7	-	-
23	H05504	Mahalakshmi.G	18/f	6100	5100	73	60	18	32	9	8	-	-
24	I14630	Lalitha.R	48/f	7000	5200	54	50	40	44	6	6	-	-
25	I19581	Arumugam.	42/m	6800	8800	63	62	28	28	9	6	-	-
26	H96522	Lakshmi.N	35/f	4700	4600	49	50	45	41	5	9	-	-
27	H08542	Renuga.R	45/f	6500	6400	60	60	33	33	2	7	5	-
28	I32663	Dinesh kumar	22/m	9000	8300	55	60	41	37	4	3	-	-
29	H95579	Giriprasad.R	35/m	6600	7800	51	60	42	33	0	0	7	7
30	F012880	Devagi.K	49/f	5800	7900	50	50	43	45	-	-	7	5

S. NO	OP NO	NAME	A/S	TC		DC							
						P	P	L	L	M	M	E	E
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
31	H11925	Vetrivendhan.K	46/m	6100	7200	50	45	43	39	-	-	7	6
32	I12205	Gokulapriya .B	24/f	9200	8000	61	55	36	40	-	-	3	5
33	H38977	Kotteswari	41/f	9700	9300	59	60	37	35	0	0	3	5
34	H94023	Shagul.M	32/m	9100	8200	62	60	30	30	0	0	8	5
35	H83322	Thameemansari	18/m	5000	5500	55	58	41	40	0	0	4	1
36	I58910	Alamelu.R	33/f	8500	8300	45	51	39	42	-	-	12	5
37	I58012	Logesh.B	20/m	6800	7800	50	60	38	34	2	6	10	-
38	I44764	Vadivelu.n	30/m	5700	5900	55	61	33	33	0	0	8	6
39	G69634	Loganayagi.D	30/f	8100	7900	55	55	40	42	0	0	5	3
40	G86703	Loganathan.	37/m	7900	9700	59	70	35	25	6	5	-	-

Hemoglobin and Blood Sugar

S. NO	OP NO	NAME	A/S	Hb gm/dl		Bldsug(F) mgs%		Bldsug(PP) mgs%	
				BT	AT	BT	AT	BT	AT
1	I57950	Arun joshi.s	30/m	16.1	15.8	83	90	103	117
2	I22078	Anitha.P	26/f	13.7	14.6	72	101	96	116
3	I47497	Muruga selvi.	24/f	12.3	12.6	71	88	90	110
4	G97302	Swarnalakshmi	21/f	13	12.1	70	100	74	114
5	I41877	Sinduja.S	27/f	12.7	12.5	76	95	61	97
6	I45501	Ellammal	41/f	12.7	12.5	74	102	73	110
7	I47469	Sarala.M	27/f	10.1	10.3	81	90	77	102
8	I39449	Jayanthi.s	40/f	13.3	12.8	82	104	101	111
9	H46122	Lakshmisudha	36/f	8.9	9.6	66	102	69	104
10	I46919	Vimalkumar.N	36/m	14.7	15.4	77	100	82	120
11	I46798	Kavitha,S	28/f	10.9	10.1	77	102	97	163
12	I42082	Kavitha.T	31/f	13.5	13.3	74	94	86	130
13	I43334	Nanthini.N	24/f	13.6	13.3	63	100	74	111

14	I44446	Parameshwari	33/f	11.7	11.6	75	106	76	142
15	I38041	Manivannan.E	41/m	16.4	16.3	78	97	127	111
16	I30933	Meena.R	27/f	11.1	11.8	72	90	82	110
17	I39306	Hemavathy.N	41/f	13.2	13.8	63	101	105	145
18	I19082	Mahendran	30/m	15.5	15.5	101	86	127	105
19	H99884	Ganesh Shankar	24/m	15.6	15.1	74	103	79	106
20	I41510	Saroja.S	45/f	12.8	12.5	74	105	70	134
21	H77505	Thilagavathy.N	25/f	9.6	9.1	74	94	78	102
22	H95096	Parthiban.G	41/m	14.8	14.9	114	117	133	150
23	H05504	Mahalakshmi.G	18/f	11.4	10.1	62	96	69	101
24	I14630	Lalitha.R	48/f	14.3	13.7	65	91	100	95
25	I19581	Arumugam.	42/m	15	15.4	93	110	144	180
26	H96522	Lakshmi.N	35/f	10.2	10.4	77	98	110	102
27	H08542	Renuga.R	45/f	13.4	12.2	81	92	70	97
28	I32663	Dinesh kumar	22/m	15.3	14.6	80	83	110	152
29	H95579	Giriprasad.R	35/m	15.6	15.1	97	93	110	100
30	F012880	Devagi.K	49/f	12.6	12.5	96	96	145	160
31	H11925	Vetrivendhan.K	46/m	14.8	15.2	99	119	108	120
32	I12205	Gokulapriya .B	24/f	13	12.6	95	94	98	82
33	H38977	Kotteswari	41/f	13.1	12.2	108	97	142	132
34	H94023	Shagul.M	32/m	14	13.8	94	108	104	122
35	H83322	Thameemansari	18/m	14.9	15.2	98	102	110	112
36	I58910	Alamelu.R	33/f	9.7	9.9	92	87	122	120
37	I58012	Logesh.B	20/m	15.7	14.9	98	96	143	128
38	I44764	Vadivelu.n	30/m	11	12.7	72	86	96	110
39	G69634	Loganayagi.D	30/f	13.4	12.8	99	110	122	116
40	G86703	Loganathan.	37/m	15.1	13.9	76	99	88	110

URINE ANALYSIS

S. NO	OP NO	NAME	A/S	URINE ANALYSIS							
				Albumin		Sugar		Deposits			
								Pus cells		Epi cells	
				BT	AT	BT	AT	BT	AT	BT	AT
1	I57950	Arun joshi.s	30/m	NIL	NIL	NIL	NIL	2-4	1-2	1-2	1-2
2	I22078	Anitha.p	26/f	NIL	NIL	NIL	NIL	6-8	6-7	6-8	2-4
3	I47497	Murugaselvi.	24/f	NIL	NIL	NIL	NIL	2-4	1-2	2-4	2-4
4	G97302	Swarnalakshmi.	21/f	NIL	NIL	NIL	NIL	2-4	2-3	2-4	2-3
5	I41877	Sinduja.s	27/f	NIL	NIL	NIL	NIL	2-4	2-4	2-4	1-2
6	I45501	Ellammal.	41/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	2-4
7	I47469	Sarala.m	27/f	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2
8	I39449	Jayanthi.s	40/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	2-4
9	H46122	Lakshmisudha.	36/f	NIL	NIL	NIL	NIL	2-3	2-3	1-2	1-2
10	I46919	Vimalkumar.N	36/f	NIL	NIL	NIL	NIL	1-2	3-5	2-4	3-5
11	I46798	Kavitha.s	28/f	NIL	NIL	NIL	NIL	2-3	2-3	2-3	2-4
12	I42082	Kavitha.T	31/f	NIL	NIL	NIL	NIL	1-2	1-2	2-4	1-2
13	I43334	Nanthini.N	24/f	NIL	NIL	NIL	NIL	2-4	2-4	2-4	2-4
14	I44446	parameshwari	33/f	NIL	NIL	NIL	NIL	2-3	1-2	1-2	1-2
15	I38041	Manivannan.E	41/m	NIL	NIL	NIL	NIL	2-3	3-5	2-3	3-5
16	I30933	Meena.R	27/f	NIL	NIL	NIL	NIL	1-2	1-2	2-4	1-2
17	I39306	Hemavathy.N	41/f	NIL	NIL	NIL	NIL	3-5	2-4	2-4	2-4
18	I19082	Mahendran	30/m	NIL	NIL	NIL	NIL	3-5	2-4	1-2	1-2
19	H99884	Ganesh shankar	24/m	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2
20	I41510	Saroja.S	45/f	NIL	NIL	NIL	NIL	2-4	1-2	1-2	1-3
21	H77505	Thilagavathy.N	25/f	NIL	NIL	NIL	NIL	-	1-2	-	2-4
22	H95096	Parthiban.G	41/m	NIL	NIL	NIL	NIL	1-2	2-3	2-4	2-4
23	H05504	Mahalakshmi.G	18/f	NIL	NIL	NIL	NIL	1-2	1-2	1-3	2-4
24	I14630	Lalitha.R	48/f	NIL	NIL	NIL	NIL	1-2	3-5	2-4	2-4
25	I19581	Arumugam.	42/m	NIL	NIL	NIL	NIL	2-3	3-5	2-3	1-2
26	H96522	Lakshmi.N	35/f	NIL	NIL	NIL	NIL	2-3	1-2	2-3	1-2
27	H08542	Renuga.R	45/f	NIL	NIL	NIL	NIL	2-4	2-3	2-4	1-2

28	I32663	Dinesh kumar	22/m	NIL	NIL	NIL	NIL	1-2	2-4	2-4	2-4
29	H95779	Giriprasad .R	35/m	NIL	NIL	NIL	NIL	2-4	2-3	1-2	2-3
30	F012880	Devagi.k	49/f	NIL	NIL	NIL	NIL	2-3	2-4	2-3	1-2
31	H11925	Vetrivendhan.K	46/m	NIL	NIL	NIL	NIL	2-4	1-2	2-4	2-3
32	I12205	Gokulapriya .B	24/f	NIL	NIL	NIL	NIL	2-4	1-2	2-4	1-2
33	H38977	Kotteswari	41/f	NIL	NIL	NIL	NIL	2-4	1-3	6-8	2-4
34	H94023	Shagul.M	32/m	NIL	NIL	NIL	NIL	1-2	1-2	1-2	2-4
35	H83322	Thameemansari	18/m	NIL	NIL	NIL	NIL	-	-	1-2	2-4
36	I58910	Alamelu.R	33/f	NIL	NIL	NIL	NIL	1-2	2-4	1-2	2-4
37	I58012	Logesh.B	20/m	NIL	NIL	NIL	NIL	4-5	2-3	4-5	4-5
38	I44764	Vadivelu.n	30/m	NIL	NIL	NIL	NIL	2-3	2-4	1-2	1-2
39	G69634	Loganayagi.D	30/f	NIL	NIL	NIL	NIL	2-4	1-2	1-2	2-4
40	G86703	Loganathan.	37/m	NIL	NIL	NIL	NIL	2-4	1-2	3-5	3-5

Specific investigations :

AEC and ESR before and after treatment :

S. NO	OP NO	NAME	AGE/ SEX	AEC		ESR BT		AT	
				BT	AT	½ hr	1 hr	½ hr	1 hr
1	I57950	Arun joshi.s	30/m	188	722	6	12	6	12
2	I22078	Anitha.P	26/f	211	144	10	22	6	12
3	I47497	Muruga selvi.	24/f	144	180	6	12	5	10
4	G97302	Swarnalakshmi	21/f	270	188	6	12	2	6
5	I41877	Sinduja.S	27/f	122	100	2	4	14	30
6	I45501	Ellammal	41/f	244	100	6	12	4	10
7	I47469	Sarala.M	27/f	191	211	8	18	6	12
8	I39449	Jayanthi.s	40/f	422	188	42	82	24	52
9	H46122	Lakshmisudha	36/f	200	166	34	70	16	32
10	I46919	Vimalkumar.N	36/m	244	288	2	4	2	4
11	I46798	Kavitha,S	28/f	288	1044	10	20	2	6
12	I42082	Kavitha.T	31/f	188	322	12	24	10	20

13	I43334	Nanthini.N	24/f	144	200	16	32	12	24
14	I44446	Parameshwari	33/f	355	366	20	42	24	90
15	I38041	Manivannan.E	41/m	390	200	2	4	2	4
16	I30933	Meena.R	27/f	711	580	4	8	8	16
17	I39306	Hemavathy.N	41/f	166	44	42	84	32	64
18	I19082	Mahendran	30/m	155	44	2	6	2	4
19	H99884	Ganesh Shankar	24/m	299	166	2	4	2	4
20	I41510	Saroja.S	45/f	288	400	24	50	24	50
21	H77505	Thilagavathy.N	25/f	311	288	16	32	12	24
22	H95096	Parthiban.G	41/m	188	160	6	12	2	4
23	H05504	Mahalakshmi.G	18/f	254	133	10	22	2	6
24	I14630	Lalitha.R	48/f	211	155	6	14	6	12
25	I19581	Arumugam.	42/m	377	388	8	18	8	16
26	H96522	Lakshmi.N	35/f	144	311	4	8	10	22
27	H08542	Renuga.R	45/f	255	188	6	12	6	12
28	I32663	Dinesh kumar	22/m	44	133	4	10	24	50
29	H95579	Giriprasad.R	35/m	99	311	2	4	2	6
30	F012880	Devagi.K	49/f	166	144	12	24	14	30
31	H11925	Vetrivendhan.K	46/m	566	410	2	4	8	16
32	I12205	Gokulapriya .B	24/f	66	144	12	24	10	20
33	H38977	Kotteswari	41/f	299	188	20	42	30	60
34	H94023	Shagul.M	32/m	88	144	22	46	12	8
35	H83322	Thameemansari	18/m	144	102	2	4	8	16
36	I58910	Alamelu.R	33/f	102	899	40	82	12	26
37	I58012	Logesh.B	20/m	922	188	4	8	6	12
38	I44764	Vadivelu.n	30/m	977	199	8	16	6	12
39	G69634	Loganayagi.D	30/f	166	240	10	20	12	16
40	G86703	Loganathan.	37/m	188	199	2	4	20	40

ANALYSIS OF TRIAL DRUG

CHEMICAL ANALYSIS

Preparation of extract:

25 ml of samuthra pazha nei is measured accurately and placed in a 250 ml of clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water.

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1.	Appearance of the sample	Straw color	
I.	**Test For Acid Radicles**		
1.	**Test for Sulphate**: 2 ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution.	No cloudy appearance.	Absence of Sulphate.
2.	**Test for Chloride:** 2 ml of the above prepared extract is added with dil. Hno_3 till the effervescence ceases. Then 2 ml of silver nitrate solution is added.	Cloudy appearance present.	**Presence of Chloride.**
3.	**Test for Phosphate:** 2ml of the extract is treated with 2ml of ammonium molybdate solution and 2ml of con.Hno_3.	No cloudy yellow appearance.	Absence of Phosphate.
4.	**Test for Carbonate:** 2ml of the extract is treated with 2ml magnesium sulphate solution.	Cloudy appearance present.	**Presence of Carbonate.**
5.	**Test for Nitrate:** 1 drop of the substance is heated with copper turnics and concentrated H_2SO_4 and viewed the test tube vertically down.	No characteristic changes.	Absence of nitrate.

6.	**Test for Sulphide:** 1 ml of the substance is treated with 2 ml of con.HCL.	No rotten egg smelling gas evolved.	Absence of Sulphide.
7.	**Test for Fluride & Oxalate:** 2 ml of the extract is added with 2ml of dil. Acetic acid and 2 ml calcium chloride solution and heated.	No cloudy appearance.	Absence of Fluride and Oxalate.
8.	**Test for Nitrite:** 3 drops of the extract is placed on filter paper on that 2 drops of acetic acid and 2 drops Benzidine solution is placed.	No characteristic changes.	Absence of Nitrite.
9.	**Test for Borate:** 2 pinches of the substance is made into paste by using sulphuric acid and alcohol (95%) and introducer into the blue flame.	Bluish green color flame not appeared.	Absence of Borate.
II.	**Test for Basic Radicles**		
1.	**Test for Lead:** 2 ml of the extract is added with 2 ml of Potassium iodide solution.	No yellow precipitate is obtained.	Absence of Lead.
2.	**Test for Copper:** One pinch of substance is made into paste with con.HCL in a watch glass and introduced into the non-luminous part of the flame.	No blue color flame.	Absence of copper.
3.	**Test for Aluminum:** To the 2ml of the extract sodium hydroxide is added in drops to excess.	No characteristic changes.	Absence of Aluminium.
4.	**Test for Iron:** a. To the 2 ml of extract add 2 ml of ammonium thiocynate solution.	Mild red color appeared.	**Presence of Iron.**

	b. To the 2ml of extract 2 ml ammonium thiocynate solution and 2 ml of con.HNO_3 is added.	Blood red color appeared.	**Presence of Iron.**
5.	**Test for Zinc:** To 2ml of the extract sodium hydroxide solution is added in drops to excess.	White precipitate is not appeared.	Absence of zinc.
6.	**Test for Calcium:** 2 ml of the extract is added with 2ml of 4% ammonium oxalate solution.	No Cloudy appearance.	Absence of Calcium.
7.	**Test for Magnesium:** To 2ml of extract sodium hydroxide solution is added in drops to excess.	No white precipitate.	Absence of magnesium.
8.	**Test for Ammonium:** To 2 ml of extract few ml of Nessler's reagent and excess of sodium hydroxide solution are added.	No brown color appeared.	Absence of ammonium.
9.	**Test for Potassium:** 1 ml of substance is treated with 2ml of sodium nitrate solution and then treated with 2ml of cobalt nitrate in 30% glacial acetic acid.	Yellowish precipitate is obtained.	**Presence of potassium.**
10.	**Test for Sodium:** 2 pinches of the substance is made into paste by using HCL and introduced into the blue flame of Bunsen burner.	No yellow color flame appeared.	Absence of sodium.
11.	**Test for Mercury:** 2 ml of the extract is treated with 2 ml of sodium hydroxide solution.	No yellow precipitate is appeared.	Absence of mercury.

12.	**Test for Arsenic**: 2 ml of the extract is treated with 2 ml of sodium hydroxide solution.	No brownish red precipitate is obtained.	Absence of Arsenic.
III.	**Miscellanious**		
1.	**Test for Starch:** 2ml of the extract is treated with weak iodine solution.	No blue color developed.	Absence of starch.
2.	**Test for Reducing sugar**: 5 ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for two minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The color changes are noted.	No brick red color developed.	Absence of Reducing sugar.
3.	**Test for the Alkaloids**: 2 ml of extract is treated with 2 ml of picric acid.	Yellow color developed.	**Presence of Alkaloid.**
4.	**Test for Tannic acid**: 2 ml of extract is treated with 2 ml of ferric chloride solution.	No Black color precipitate is obtained.	Absence of tannic acid.
5.	**Test for Unsaturated compound:** To the 2 ml of extract 2 ml of Potassium permanganate solution is added.	Potassium permanganate is not decolorized.	Absence of Unsaturated compound.
6.	**Test for Amino acid**: 2 drops of the extract is placed on a filter paper and dried well.	No violet color developed.	Absence of amino acid.

7.	**Test for Type of Compound**: 2 ml of the extract is treated 2 ml of ferric chloride solution.	No green color developed.	Absence of oxyquinole epinephrine and pyro catechol.
		No red color developed.	Anti pyrine, Aliphatic amino acids and meconic acid are absent.
		No violet color developed.	Apomorphine salicylate and Resorcinol are absent.
		No blue color developed.	Morphine, Phenol cresol and hydro quinine are absent.

Result:

The chemical study of the trial drug reveals Chloride, Carbonate, Iron, potassium Alkaloid.

Physicochemical evaluation of Samuthra pazha nei

Project ID : NRS/AS/0029/02/2017

Institute : National Institute of siddha ,Chennai

Sample Name : Samuthra Pazha Nei

Sample ID : SPN

Percentage Loss on Drying

10gm of test drug was accurately weighed in evaporating dish .The sample was dried at 105oC for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

Determination of Total Ash

3 g of test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of pH

Sample being oily in nature the direct litmus evaluation method was adopted to check the pH of the sample.

Determination of Iodine value

About 20 gm of SPN was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this about 25 ml of Wiji's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mins and refrigerated for an hour.T About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value

About 2 gm of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeatthe same procedure without taking the sample for blank titration . Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

Final Test report

Parameter	**Observation**
Color	Yellowish
Smell	Pleasant Chracteristic
Touch	Greasy

S.No	**Parameter**	**Mean (n=3) SD**
1	Loss on Drying at 105 °C (%)	16.7 ± 1.11
2	Total Ash (%)	1.38 ± 0.13
S.No	**Specific Test**	**SPN**
1.	pH	6
	Refractive index	1.44
	Iodoine value (mg I2/g)	125
	Saponification Value (mg of KOH to saponify 1gm of fat)	218

Reference:

1. India Pharmacopeia I Volume I, Government of India, Ministry of Health and Family welfare, Indian Pharmacopeia commission, 2014.

2. Pharmacopoeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of indian medicine which include drugs of Ayurveda, Unani and Siddha systems. Department AYUSH .Ministry of Health & Family Welfare, Govt. of India

3. Indian standard methods of sampling and test for oils and fats Indian standard institution New Delhi 47-50. 1964

PHYTOCHEMICAL ANALYSIS OF SAMUTHIRA PAZHA NEI

Sample Preparation

Samuthra Pazha Nei (SPN) was extracted with hexane and the extract was subjected to the following analysis

Test for Alkaloid- Mayer's reagent

To the test drug about 2ml of Mayer's reagent was added and was observed for the presence of alkaloids. Appearance of dull white precipitate indicates the presence of alkaloids.

Test for flavonoid

To 0.1ml of the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for Glycosides - Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for Triterepnoids

To the test solution 2ml chloroform was added with few drops of conc. Sulphuric acid (3ml) at the side of the test tube. An interface with a reddish brown coloration is formed if terpenoids constituent is present.

Test for Steroids - Salkowski test

To the test solution 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer

Showed yellow with green fluorescence. It showed the presence of steroids.

Test for Carbohydrates - Benedict's test

To 0.5 ml of test drug about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

Test – Phenol- Lead acetate test

The test sample is dissolved in of distilled water and to this 3 ml of 10% lead acetate solution is added. A bulky white or creamy yellowish precipitate indicates the presence of phenolic compounds.

Test for tannins

About 0.5ml of test sample is boiled in 20 mL of distilled water in a test tube and then filtered. The filtration method used here is the normal method, which includes a conical flask and filter paper. The 0.1% FeCl3 is added to the filtered samples and observed for brownish green or a blue black coloration, which shows the presence of tannins

Test for Saponins

The test drugs were shaken with water vigorously for 10 mins , copious lather formation indicates the presence of saponins.

Test for Proteins (Biuret Test)

Biuret test: Equal volume of 5% solution of sodium hydroxide and 1% copper sulphate were added. Appearance of pink or purple colour indicates the presence of proteins and free amino acids.

Test of Coumarins

1 ml of extract, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for Quinones

The test samples were treated separately with Alc. KOH solution. Appearance of colors ranging from red to blue indicates the presence of Quinones.

Test for Anthocyanin

About 0.2 ml of the extract was weighed in separate test tube, 1ml of 2N Sodium hydroxide was added, and heated for 5 minutes at 100 ± 2°C. Observed for the formation of bluish green color which indicates the presence of anthocyanin.

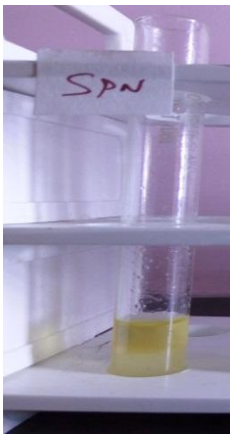
Test for Betacyanin

To 2 ml of the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100□C. Formation of yellow colour indicates the presence of betacyanin.

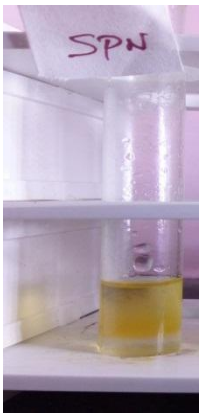
Reference

Brain KR, Turner TD. The Practical Evaluation of Phytopharmaceuticals. Bristol: Wright- Scientechnica; 1975:36-45

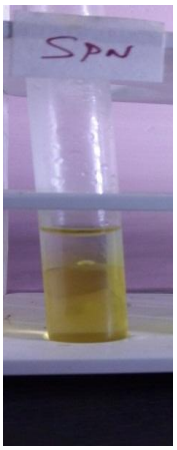
RESULTS



Test for Alkaloid- Mayer's reagent



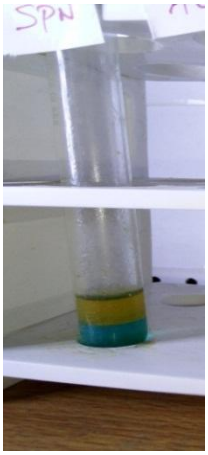
Test for flavonoid



Test for Glycosides - Borntrager's Test

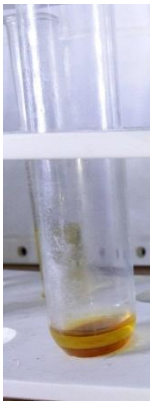
Test for Triterepnoids

Test for Steroids - Salkowski test



Test for Carbohydrates - Benedict's test

Test – Phenol- Lead acetate test

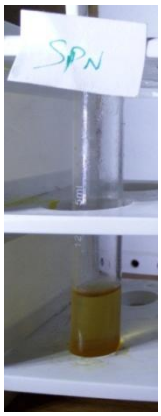


Test for tannins

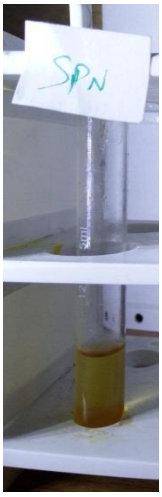
Test for Saponins

Test for Proteins (Biuret Test)

Test of Coumarins



Test for Quinones



Test for Anthocyanin

Test for Betacyanin

PHYTOCOMPONENTS	SPN
ALKALOIDS	+
FLAVONOIDS	+
GLYCOSIDES	+
STEROIDS	+
SUGAR	-
TRITEREPNOIDS	-
COUMARINS	+
PHENOLS	+
TANNINS	-
SAPONINS	+
PROTEINS	+
ANTHOCYANIN	-
BETACYANIN	-
QUINONES	-

+ Indicates positive

- Indicates Negative

Quantitative estimation of phytoconstituents of SAMUTHRA PAZHA NEI

Determination of total Phenol content

The total phenol content was determined using Folin–Ciocalteu reagents with analytical grade Gallic acid as the standard. 1 ml of sample was added to deionized water (10 ml) and Folin–Ciocalteu phenol reagents (1ml). After 5 minutes, 20% sodium carbonate (2 ml) was added to the mixture. After being kept in total darkness for 1 hr, the absorbance was measured at 750 nm using a spectrophotometer. Amounts of total Phenol was calculated using Gallic acid calibration curve. The results were expressed as Gallic acid equivalents (GAE) mg/g of dry plant matter.

Reference

Ganesh N. Sharma K, Nitin S, Jyotsana S. Phytochemical screening and estimation of Total Phenolic Content in Aegle marmelos Seeds. Int J Pharma Clinc Res.2011; 3(2): 27-29.

Total Flavonoid

Total flavonoid content in the drug SPN was determined using aluminum chloride method . In this method Quercetin was used as standard and flavonoid contents were measured as quercetin equivalent. For this purpose, the calibration curve of quercetin was drawn. 1ml of standard or sample SPN was taken into 10ml volumetric flask, containing 4ml of distill water. 0.3ml of 5%$NaNO_2$ added to the flask. After 5min, 0.3ml 10%$AlCl_3$ was added to the mixture. At the 6th min add 2ml of 1M NaOH was added and volume made up to 10ml with distills water. The absorbance was noted at 510nm using UV-Visible spectrophotometer.

Reference

Olajire A. A and Azeez L Total antioxidant activity, phenolic, flavonoid and ascorbic acid contents of Nigerian vegetables., 2011; 2(2) 022-029,African Journal of Food Science and Technology

Estimation of Alkaloid

SPN weight equivalent to 5 gm was weighed into a 250 ml beaker and 200 ml of 10% acetic acid in ethanol was added and covered and allowed to stand for 4 hr. This was filtered and the extract was concentrated on a water bath to one-quarter of the original volume. Concentrated ammonium hydroxide was added drop wise to the extract until the precipitation was complete. The whole solution was allowed to settle and the precipitated was collected and washed with dilute ammonium hydroxide and then filtered. The residue is the alkaloid, which was dried and weighed.

Reference

Ganga rao B, Umamaheswara rao, Sambasiva rao, Mallikarjuna rao T. Studies on phyto chemical constituents, quantification of total phenol, alkaloid content and In-vitro anti-oxidant activity of Coccinia cordifolia. Int. J. pharm. life sci.2011; 2(10):1177-1182.

Phyto- constituents	SPN
Total phenols (GAE mg/gm)	0.70 ± 0.125
Total flavanoids (Quercetin mg/gm)	0.30 ± 0.01
Total alkaloids(mg/gm)	0.22 ± 0.03

Mean with 3 replicates ± SD.

GCMS- Analysis of Samuthra pazha nei

GCMS (Clarus 500 Perkin – elmer (Auto system XL)), NIST Ver.2.1 MS data library

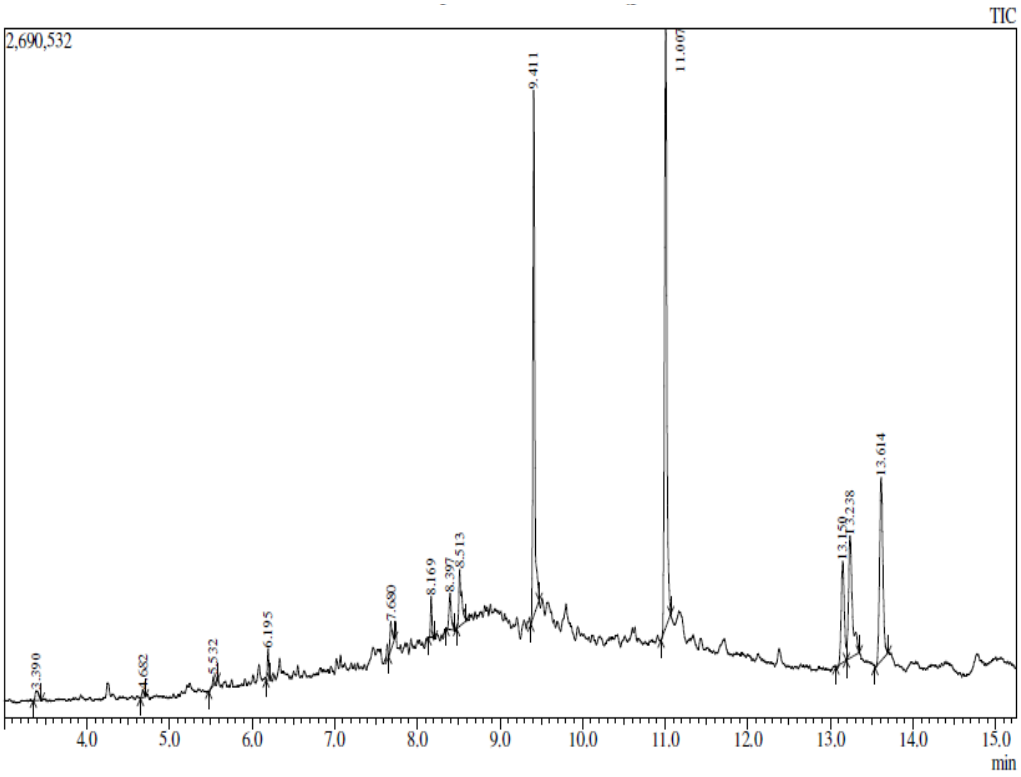
Specification :

Start Time(min)	End Time(min)	Start m/z	End m/z	Scan	Speed
2.50	18.00	50.00	650.00	2000	

Sample Inlet Unit: GC

GC-MS Plays a key role in the analysis of unknown components of plant origin. GC-MS ionizes compound and measures their mass numbers. Ionization method includes EI (Electron Ionization). The EI method produces ions by colliding thermal electrons emitted from a filament with sample gas molecules. This method provides high stability in ionization and obtained mass spectra show good reproducibility. The EI method provides good result for quantitative analysis as well. Quantitative analysis with GC-MS, in which only ions specific to the compounds are measured, is highly selective method without interfering components. Gas chromatography Technique involves the separation of volatile components in a test sample using suitable capillary column coated with polar or non-polar or intermediate polar chemicals. Elite-1 column (100% Dimethyl polysiloxane) is a non-polar column used for analysis of phyto-components. Elite -5 column (5% phenyl and 95% methyl polysiloxane) is an intermediate column and also used for the estimation of Phytochemical. An inert gas such as hydrogen or nitrogen or helium is used as a carrier gas .The compounds of test sample is evaporated in the injection port of the GC equipment and segregated in the column by absorption and adsorption technique with suitable GC programme.

GC-MS CHROMATOGRAM OF SPN

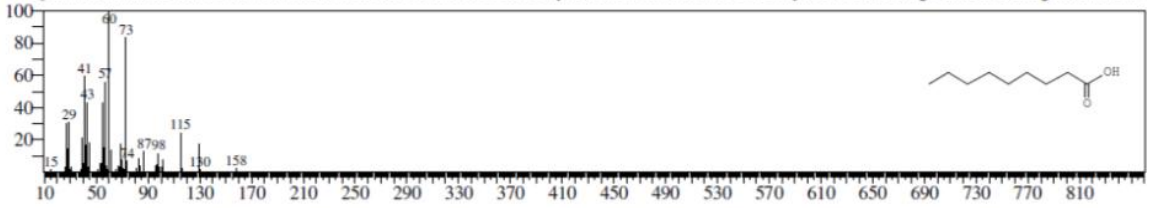


Peak Report of SPN

Peak#	R.Time	Area	Area%	Height	Height%	
1	3.390	3.355	105601	0.76	37026	0.54
2	4.682	4.650	56219	0.41	29514	0.43
3	5.532	5.475	28827	0.21	33675	0.49
4	6.195	6.170	143272	1.04	122182	1.79
5	7.680	7.655	218871	1.58	113234	1.66
6	8.169	8.130	184523	1.33	162778	2.38
7	8.397	8.350	269852	1.95	139579	2.04
8	8.513	8.475	538875	3.90	220527	3.23
9	9.411	9.375	3051901	22.07	2050660	29.99
10	11.007	10.950	4601577	33.27	2340215	34.22
11	13.150	13.065	1028002	7.43	396405	5.80
12	13.238	13.195	1566060	11.32	477751	6.99
13	13.614	13.540	2037353	14.73	714438	10.45
			13830933	100.00	6837984	100.00

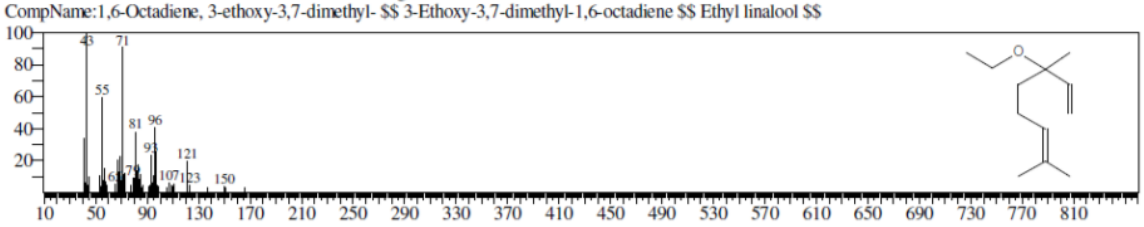
PEAK 1

Hit#:1 Entry:10005 Library:NIST05s.LIB
SI:80 Formula:C9H18O2 CAS:112-05-0 MolWeight:158 RetIndex:1272
CompName:Nonanoic acid $$ n-Nonanoic acid $$ n-Nonoic acid $$ n-Nonylic acid $$ Nonoic acid $$ Nonylic acid $$ Pelargic acid $$ Pelargonic acid $$



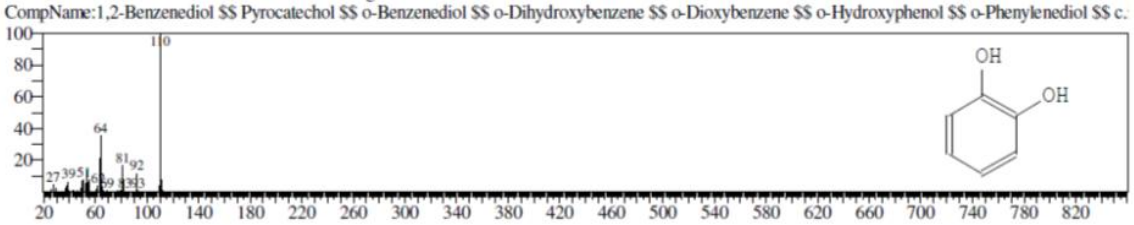
PEAK 2

Hit#:1 Entry:31245 Library:NIST05.LIB
SI:80 Formula:C12H22O CAS:72845-33-1 MolWeight:182 RetIndex:1181
CompName:1,6-Octadiene, 3-ethoxy-3,7-dimethyl- $$ 3-Ethoxy-3,7-dimethyl-1,6-octadiene $$ Ethyl linalool $$



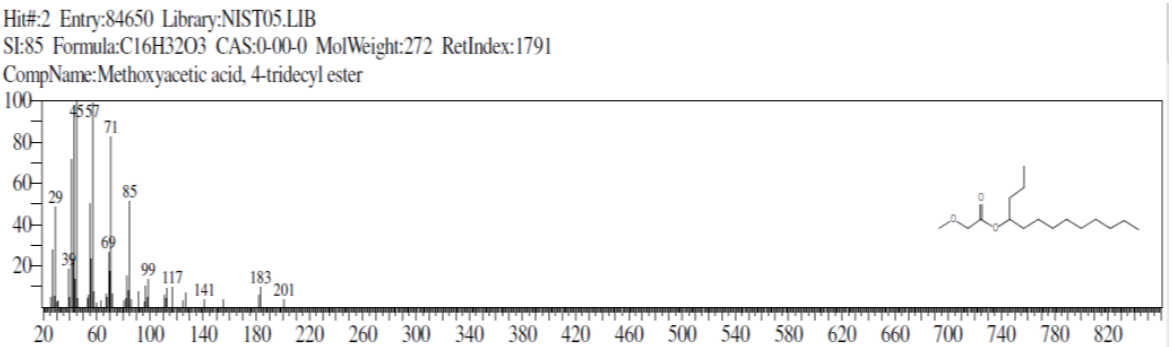
PEAK 3

Hit#:1 Entry:2576 Library:NIST05s.LIB
SI:76 Formula:C6H6O2 CAS:120-80-9 MolWeight:110 RetIndex:1122
CompName:1,2-Benzenediol $$ Pyrocatechol $$ o-Benzenediol $$ o-Dihydroxybenzene $$ o-Dioxybenzene $$ o-Hydroxyphenol $$ o-Phenylenediol $$ c.



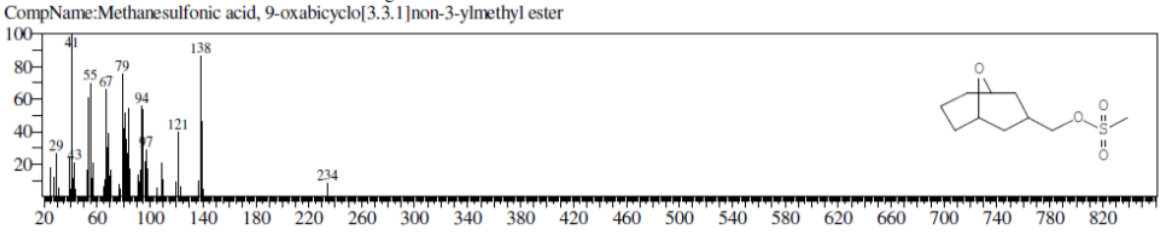
PEAK 4

Hit#:2 Entry:84650 Library:NIST05.LIB
SI:85 Formula:C16H32O3 CAS:0-00-0 MolWeight:272 RetIndex:1791
CompName:Methoxyacetic acid, 4-tridecyl ester



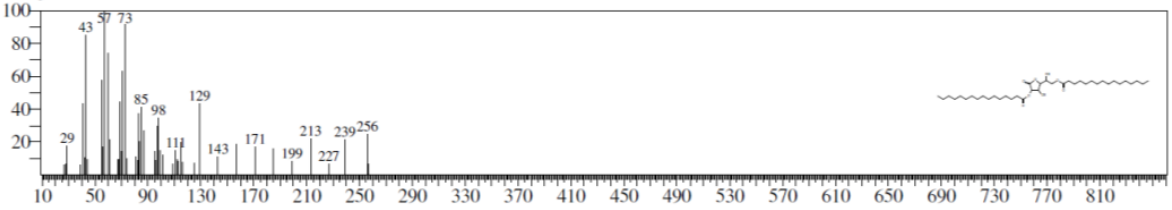
PEAK 5

Hit#:2 Entry:61193 Library:NIST05.LIB
SI:74 Formula:C10H18O4S CAS:0-00-0 MolWeight:234 RetIndex:1713
CompName:Methanesulfonic acid, 9-oxabicyclo[3.3.1]non-3-ylmethyl ester



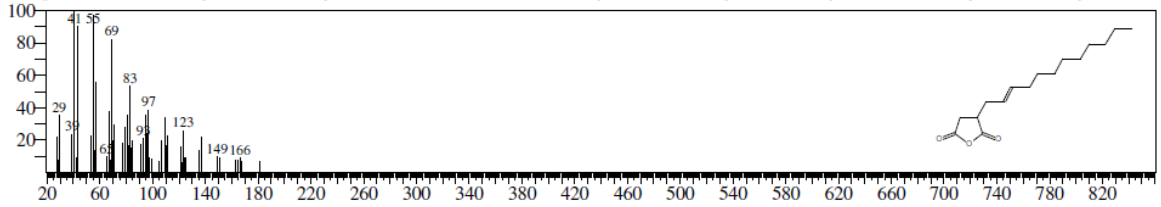
PEAK 6

Hit#:5 Entry:161860 Library:NIST05.LIB
SI:78 Formula:C38H68O8 CAS:28474-90-0 MolWeight:652 RetIndex:4765
CompName:l-(+)-Ascorbic acid 2,6-dihexadecanoate



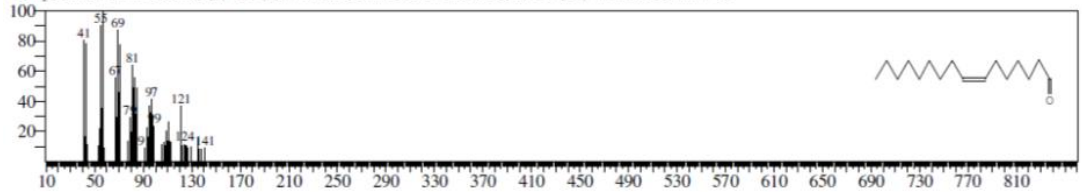
PEAK 7

Hit#:1 Entry:80765 Library:NIST05.LIB
SI:77 Formula:C16H26O3 CAS:19780-11-1 MolWeight:266 RetIndex:2159
CompName:2-Dodecen-1-yl(-)succinic anhydride $$ 2,5-Furandione, 3-dodecenyl- $$ n-Dodecenylsuccinic anhydride $$ Dodecenyl succinic anhydride $$



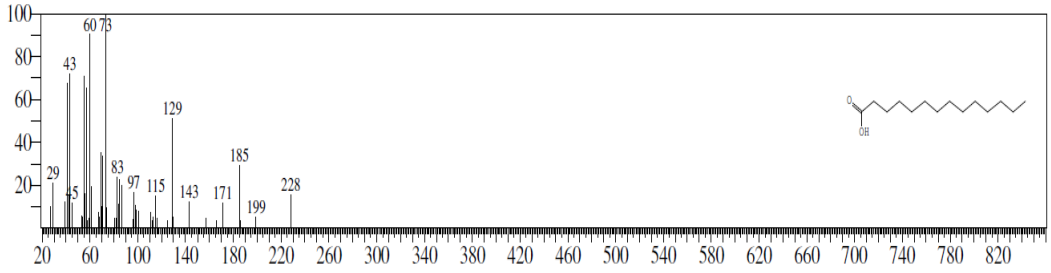
PEAK 8

Hit#:1 Entry:20038 Library:NIST05s.LIB
SI:77 Formula:C16H30O CAS:56797-40-1 MolWeight:238 RetIndex:1808
CompName:7-Hexadecenal, (Z)- $$ (Z)-7-Hexadecenal $$ Z-7-Hexadecenal $$ (7Z)-7-Hexadecenal # $$



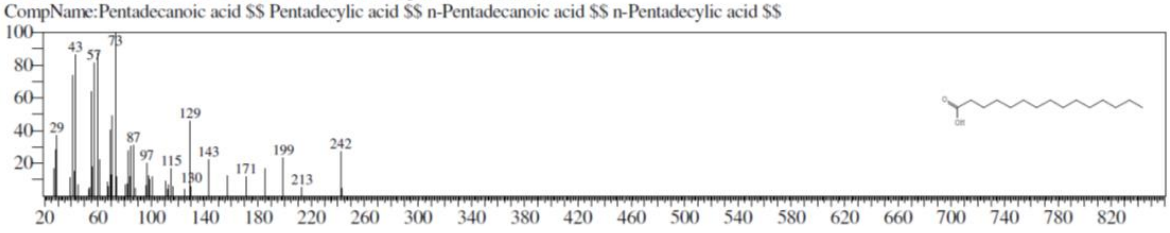
PEAK 9

Hit#:1 Entry:19252 Library:NIST05s.LIB
SI:93 Formula:C14H28O2 CAS:544-63-8 MolWeight:228 RetIndex:1769
CompName:Tetradecanoic acid $$ Myristic acid $$ n-Tetradecanoic acid $$ n-Tetradecoic acid $$ Neo-Fat 14 $$ Univol U 316S $$ 1-Tridecanecarboxylic



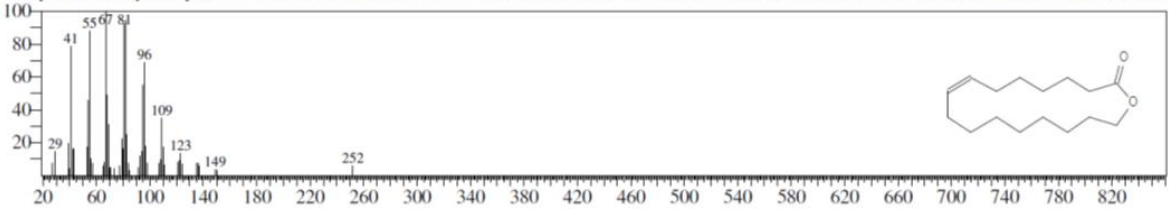
PEAK 10

Hit#:2 Entry:20371 Library:NIST05s.LIB
SI:92 Formula:C15H30O2 CAS:1002-84-2 MolWeight:242 RetIndex:1869
CompName:Pentadecanoic acid $$ Pentadecylic acid $$ n-Pentadecanoic acid $$ n-Pentadecylic acid $$



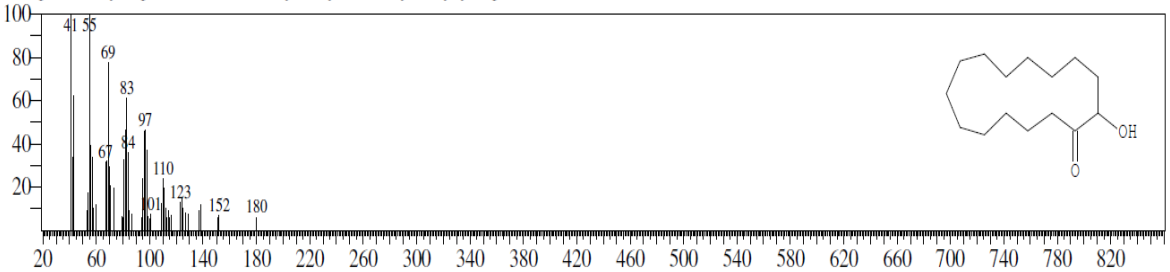
PEAK 11

Hit#:2 Entry:72510 Library:NIST05.LIB
SI:91 Formula:C16H28O2 CAS:123-69-3 MolWeight:252 RetIndex:2246
CompName:Oxacycloheptadec-8-en-2-one $$ Ambrettolid $$ Ambrettolide $$ Musk ambrette $$ Musk ambrette, natural $$ Musk natural $$ 7-Hexadeceno



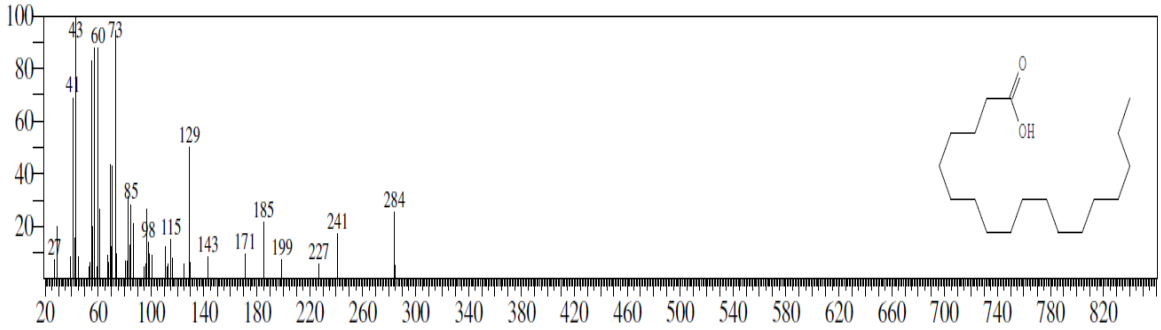
PEAK 12

Hit#:2 Entry:65295 Library:NIST05.LIB
SI:90 Formula:C15H28O2 CAS:4727-18-8 MolWeight:240 RetIndex:2158
CompName:Cyclopentadecanone, 2-hydroxy- $$ 2-Hydroxycyclopentadecanone # $$



PEAK 13

Hit#:1 Entry:22979 Library:NIST05s.LIB
SI:90 Formula:C18H36O2 CAS:57-11-4 MolWeight:284 RetIndex:2167
CompName:Octadecanoic acid $$ Stearic acid $$ n-Octadecanoic acid $$ Humko Industrene R $$ Hydrofol Acid 150 $$ Hystrene S-97 $$ Hystrene T-70 $



TLC Analysis of Samuthra pazha nei

Project ID : NRS/AS/0024/02/2017

Institute : National Institute of Siddha

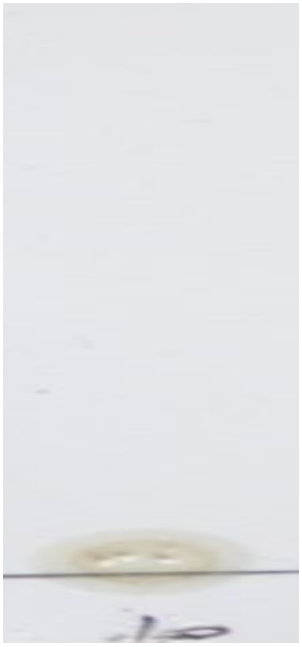
Sample Name : Samuthra Pazha Nei

Sample ID : SPN

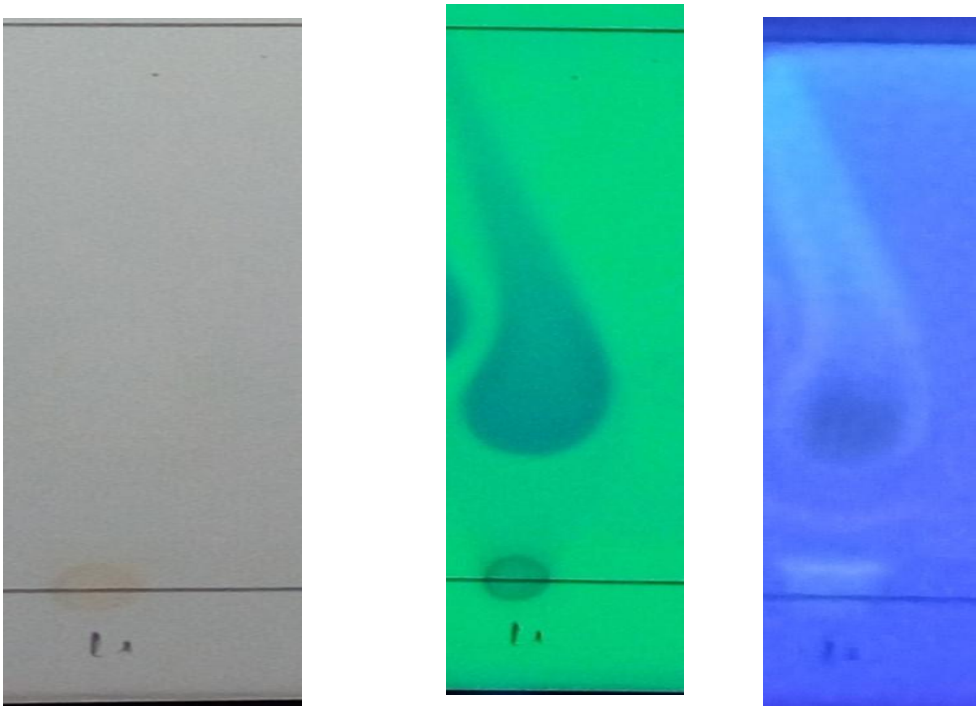
TLC Analysis

Test sample SPN was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Ethyl acetate: Methanol: Water (100:13.5:10) After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm

Sample Spotting



Visible **Short UV** **Long UV**



Reference

Lukasz Komsta, Monika Waksmundzka-Hajnos, Joseph Sherma .Thin Layer Chromatography in Drug Analysis .CRC Press, Taylor and Francis.

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

Reference

1. Wagner H. Plant Drug Analysis. A thin Layer chromatography Atlas.2nd ed. Heidelberg: Springer-Verlag Belgium; 2002:305, 227.

HPTLC Chromatographic condition

Sample : SPN

Derivatization Solvent :Anisaldehyde

Stationary phase : Silica gel GF254

Mobile phase : Chloroform : Hexane: methanol (6:3:1)

Scanning wavelength : 200-400 nm

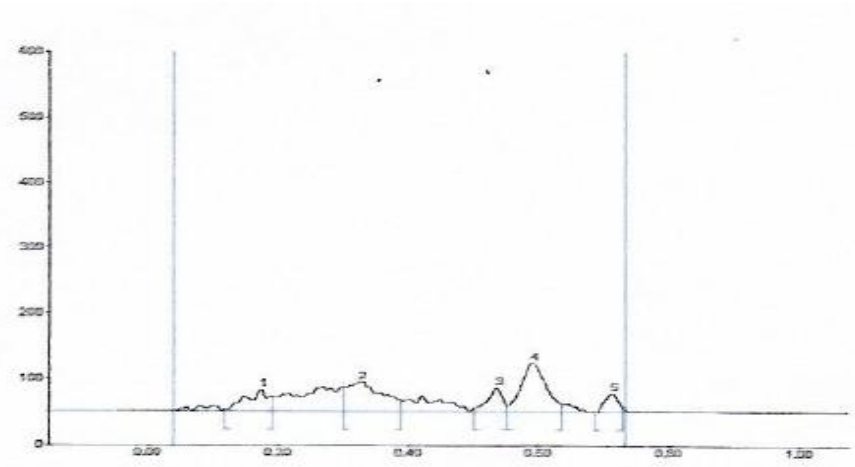
Sample concentration : 10mg/ml

Applied volume : 5 µl

Application mode : CAMAG HPTLC

TLC CHROMATOGRAM OF SPN

HPTLC CHROMATOGRAM OF SPN



Peak Table of HPTLC finger printing of SPN

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.12	1.8	0.17	33.5	15.45	0.19	21.1	876.5	14.93
2	0.30	35.7	0.32	44.7	20.66	0.39	16.0	1797.2	30.62
3	0.50	5.9	0.54	35.9	16.57	0.55	8.7	611.4	10.42
4	0.56	10.2	0.59	74.6	34.43	0.64	11.0	2153.7	36.69
5	0.69	0.1	0.71	27.9	12.89	0.73	3.5	431.2	7.35

In-vitro Anti-Inflammatory Activity by Protein (Albumin) denaturation Assay

Project ID : NRS/AS/0029/02/2017

Institute : National Institute of Siddha

Sample Name :SamuthraPazhaNei

Sample ID : SPN

Sample Stock prepared using Hexane

Albumin Denaturation Assay Procedure

In-vitro anti-inflammatory activity SamuthraPazhaNei(SPN) was studied using albumin denaturation technique. The reaction mixture consisted of bovine serum albumin (5% aqueous solution) and test sample SPN at varying concentration ranges from 100 to 500 mcg/ml and standard diclofenac sodium at the concentration of100 mcg/ml of final volume. pH was adjusted by using a small amount of 1N Hydrochloric acid. The samples were incubated at 37°C for 20 min and then heated at 57°C for 3 min. After cooling the sample, 2.5 ml of phosphate buffer solution was added into each test tube. Turbidity developed was measured spectrophoto-metrically at 660 nm, for control distilled water was used instead of test sample while product control tests lacked bovine serum albumin. The experiment was performed in triplicate.

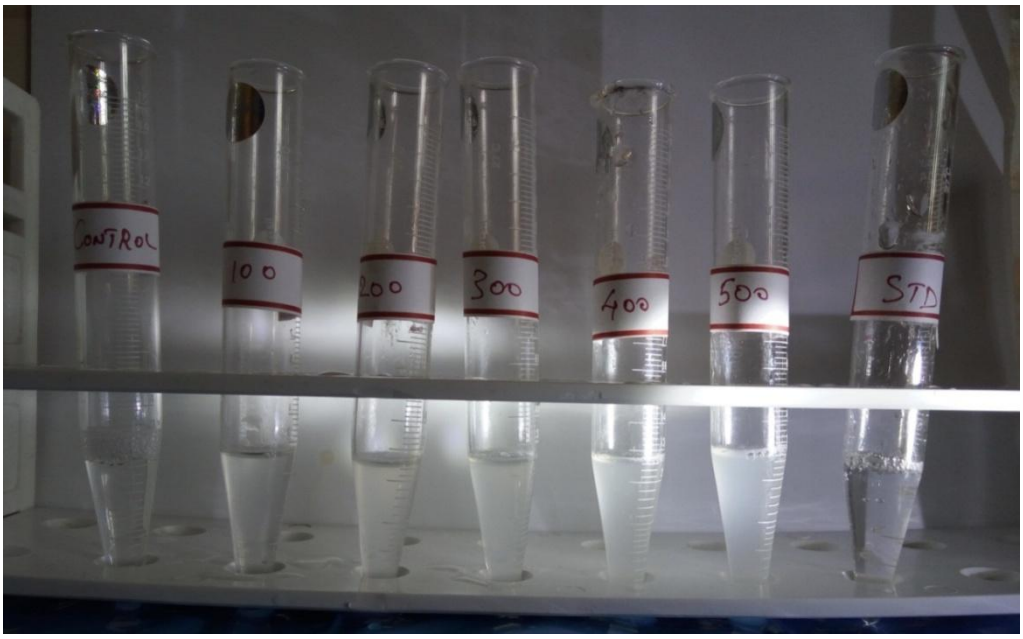
The Percentage protection from denaturation is calculated by using the formulae

$$\left[\frac{(A)_{\text{control}} - (A)_{\text{sample}}}{(A)_{\text{control}}}\right] \times 100.$$

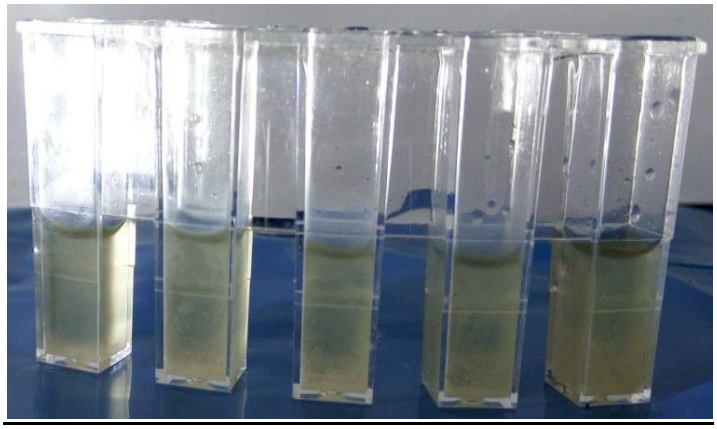
Statistical analysis

Results are expressed as Mean ± SD. The difference between experimental groups was compared by One-Way Analysis Of Variance (ANOVA) followed by Dunnet Multiple comparison test

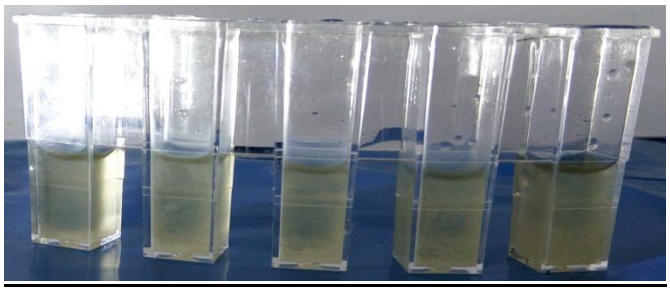
Preparation of Test and control



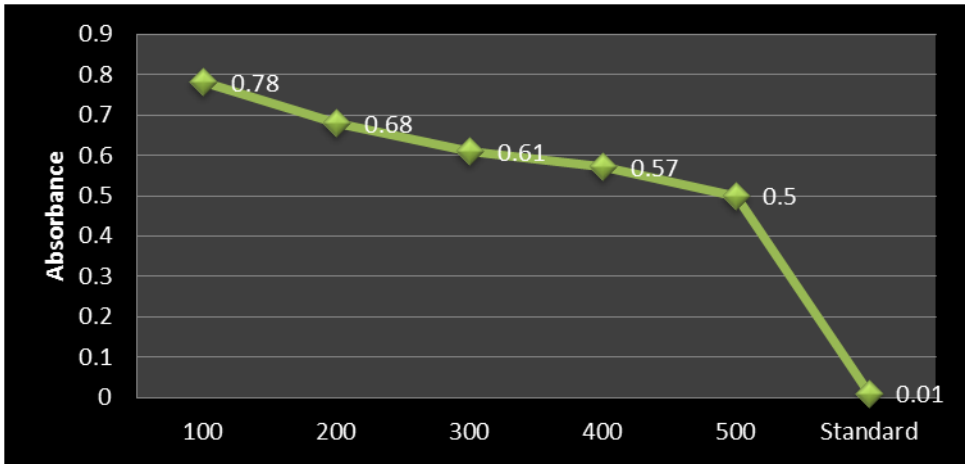
Absorbance of reaction mixture – Test Sample



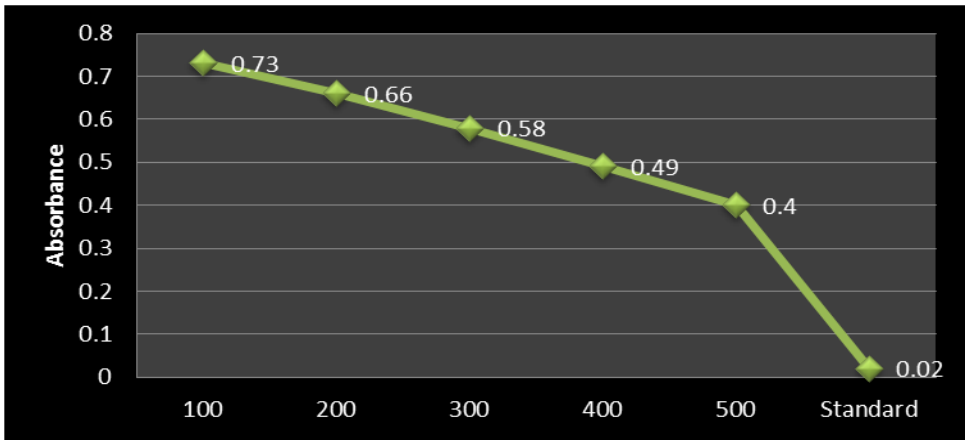
Absorbance of reaction mixture – Control and Standard



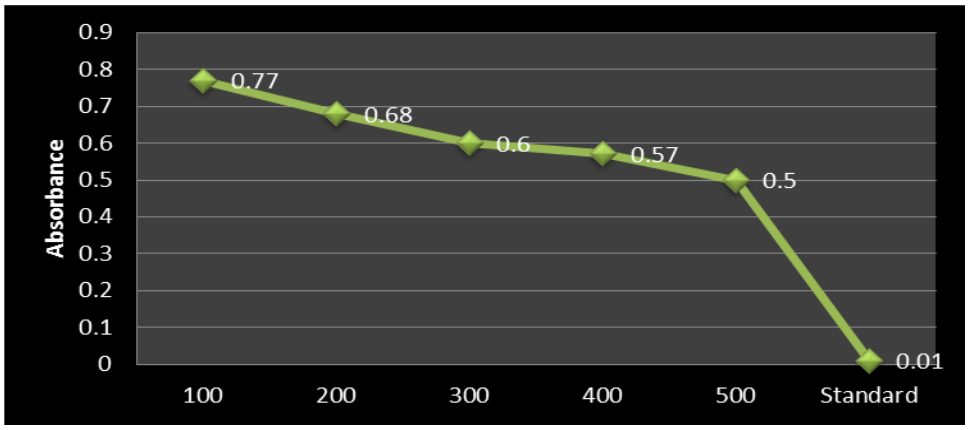
Absorbance Range of test and standard at Trial 1



Absorbance Range of test and standard at Trial 2



Absorbance Range of test and standard at Trial 3



FINAL RESULT

Concentration in µg/ml	**Absorbance**
Control	0.88 ± 0.02
SPN 100	0.76 ± 0.026
SPN 200	0.67 ± 0.011
SPN 300	0.59 ± 0.015
SPN 400	0.54 ± 0.046
SPN 500	0.46 ± 0.057
Diclofenac sodium(100 µg)	0.01 ± 0.005

Each value represents the mean ± SD. N=3

Concentration in µg/ml	Percentage Inhibition of Protein Denaturation
SPN 100	2.30 ± 1.85
SPN 200	12.1 ± 2.63
SPN 300	20.78 ± 2.40
SPN 400	26.88 ± 2.04
SPN 500	35.58 ± 3.47
Diclofenac sodium (100 µg)	86.81 ± 2.76

Each value represents the mean ± SD. N=3

Result Analysis

The result obtained from the present clearly indicates that the test drug SPN was effective in inhibiting heat induced albumin denaturation. Maximum percentage inhibition of about 35.58 % was observed at 500 µg/ml when compare to that of the Diclofenac sodium, a standard anti-inflammatory agent with the maximum inhibition 86.81 % at the concentration of 100 µg/ml.

Conclusion

From the result of the study it was concluded that the test drug SPN possess promising anti-inflammatory property in protein denaturation assay.

Reference

1. G.Leelaprakash, S.MohanDass. In-vitro anti-inflammatory activity of methanol extract of enicostemmaaxillare. Int. J. Drug Dev. & Res., 2011, 3 (3): 189-196.

2. M. V. Anoop, A. R. Bindu . In-vitro Anti-inflammatory Activity Studies on Syzygiumzeylanicum (L.) DC Leaves. International Journal of Pharma Research & Review, August 2015; 4(8):18-27.

Statistical analysis for clinical study

All corrected data were entered into MS Excel software using different columns as variable and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross tabulations were performed. The quantity variables were expressed as Mean± standard deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 'T' test was performed for determining the significance between before and after treatment.

The Mean± standard deviation of symptom score at before and after treatment were 10.07 and 2.45 respectively which is highly significant.

Treatment	Mean±Std	T Value	P Value
Before	10.07	26.68	<0.000%
After	2.45		

There is significant difference between before and after treatment i.e. 76%reduction in clinical symptoms after the treatment.

DISCUSSION

Discussion

Neer peenisam is mentioned in yugi vaithya chinthamani such as headache, lacrimation, nasal block, nasal itching, ear discharge, running nose, cough with expectoration, absence of taste may be correalated with maxillary sinusitis.

40% cases of neer peenisam were diagnosed based on clinical symptoms and x-ray paranasal sinus. All the cases were treated in outpatient department of Ayothidoss pandithar hospital, National Institute of Siddha, Tambaram, Sanatorium and Chennai 47.

The various siddha &modern methods of examination of the diseases were carried out and the data were recorded in proforma.

The trial medicine selected for internal treatment is samuthra pazha nei. The trial drug smuthra pazha nei will be given continuously for 48 days. For Op patients, they should visit the hospital once in 8 days. At each clinical visit clinical assessment is done and prognosis is noted, laboratory investigations & radiological investigation will be done on the 0^{th} day and 48^{th} day of the trial. After the end of the treatment also, the patient is advised to visit the OPD for another 2 months for follow – up.

The biochemical, pharmacological studies of the trial drug was done in the laboratories and the results were documented.

Gender distribution:

Though neer peenisam affects both male and females. Among 40 cases the prevalence of the disease was found to be higher in females (25 cases 62.5%). (Fig -1)

Age:

Among 40 cases the prevalence of disease was found to be higher among the age group of 26-33 (13 cases, 32.5%). 27.5% of cases were belongs to 34-41 age group, 25% of cases were belongs to 18-25and 15% of cases were belongs to 42-50 age group.

Occupation:

Among 40 patients, (45%) 18 cases were house wives, 5 cases (12.5%) were electricians and 4 cases (10%) were students and workers, 5% were IT profession, bank staff and jobless, 2.5% were Police, driver and driver.

Family history:

Among 40 cases, 97.5% of patients do not have any family history. Only 2.5% of patients had family history.

Diet habit:

Among the 40 cases, all of them were under Non-Vegetarian category.

Kaalam:

Among 40 cases, 57.5% of patients were in vaatha kaalam (age up to 33 years). 42.5% of patients were in Pithakaalam (age up to 34-66 years).

Chronicity of illness:

Among 40 cases, 65% patients had 18 months chronicity of illness, 20% of patients had 12-18 months chronicity, 12.5% of cases had 2-6 months chronicity and 2.5% of patients had 6-12 months chronicity.

Gunam:

Among 40 cases, all of them had Raso gunam.

Past history:

Among 40 cases, 65% of patients don't have any past history. Only 35% of cases had past history of Peenisam**.**

Triggering factor:

Among 40 cases, 60% of patients had cold exposure, 35% of patients had dust, 5% of cases had smoke as triggering factors.

Thinai:

Among 40 cases, 65% of cases were belongs to Neithal nilam, 30% of cases belongs to Marutha nilam, 5% of cases were belongs to Kurinji nilam.

Paruvakaalam:

Among 40 cases, 60% of patients were suffered in Munpanikaalam, 20% of patients were suffered in Pinpani kaalam and another 20% of cases were suffered in ilavvenil kaalam

Changes in Gnanenthiriyam:

Among 40 cases, all the patients had Nasal obstruction, temporary anosmia. 30% of patients had Dullness of both eyes, 12.5% of patients had Ear obstruction.

Changes in Kosangal:

Among 40 cases, all of them were affected with Annamayakosam, Piranamaya kosam, and Manomaya kosam in before treatment. After treatment 20% of patients were affected with Annamaya kosam and piranamayakosam, and 10% of cases were affected with manomayakosam.

Derangements of Vaatham:

Among 40 cases, before treatment all of them were affected with Piranan, Udhanan, Smaanan, Kirukaran and Devathathan, 15% of cases were affected with Abaanan, 10% of cases were affected with Viyanan, 25% of cases were affected with Koorman.

After treatment, 40% of cases were affected with Piranan, Samaanan and Kirukaran, 20% of cases were affected with Udhanan, and 7.5% of cases were affected with Devathathan.

Derangements of Pitham:

Among 40 cases, 70% of patients were affected with Aalosaga pitham in before treatment. After treatment, only 20% of patients were affected with Aalosagaptham.

Derangements of Kabam:

Among 40 cases, 65% of patients were affected with Avalambagam and Tharpagam in before treatment. After treatment it was affected in only 20% of patients.

Changes in Udal thathukkal:

Among 40 cases, 100% of patients were affected with Saaram, 30% of patients were affected with Senneer in before treatment. After treatment 20% of patients were affected with Saaram.

En vagai thervu:

Among 40 cases, 70% of patients were affected with Sparisam, 65% of patients were affected with Mozhi, 30% were affected with Vizhi, 15% were affected with Naaand 5% were affected with Malam in before treatment.

After treatment 10% of patients were affected with Sparisam and Vizhi, 20% were affected with Moizhi and 2.5% were affected with Naa.

Neerkuri and Neikkuri:

50% of Cases of Neikuri showed pitha neeer, 20% of cases of Neikuri showed vatha neer, 30% of cases of Neikuri showed kabha neer.

Clinical features:

Among 40 cases, 100% of patients had Rhinorrhoea and sneezing , 97.5% had Head ache and facial pain 75% of patients had Nasal obstruction, 35% of patients had Post nasal dripping in before treatment.

After treatment, 37.5% of patients had Rhinorrhoea and sneezing, 32.5% had head ache and facial pain and 10% had Nasal obstruction.

Chemical analysis:

The chemical study of the trial drug reveals Chloride, Carbonate, Iron, potassium, Alkaloid.

Pharmacological Study:

The Pharmacological study reveals that the trial drug has Anti-inflammatory activity.

Physico-chemical analysis, Phyto chemical analysis, Gas Chromatography with Mass Spectrometry, Thin Layer Chromatography, and High Performance Thin Layer Chromatography has also be done for trial drug.

Results:

Among 40 cases, 30% of patients showed Good improvement, 50% showed Moderate improvement, 12.5% showed Mild improvement and 7.5% showed Poor improvement.

Clinical symptoms were reduced well, but X- ray changes not markedly improved. Only 25% of cases showed reduced haziness changes in X-ray report.

SUMMARY

Summary

- The aim of the study is to evaluate the therapeutic efficacy of **Samuthra Pazha Ne**i in Neer Peenisam.
- The Protocol of this study had been submitted to Institutional Ethics Committee of National Institute of siddha. On 26-08-2015 and then approval was got from IEC for conducting this clinical study. **The IEC no is NIS/iec/9/2014-15/4-26.08.2015.**
- This clinical study was registerd in Clinical Trial Registry of India on 7-3-17**. And the CTRI NO is CTRI/2017/03/008053**
- The herbal raw drugs were purchased from raw drugs store of Paris corner and authenticated by Botanist Dr.D.Aravind,MD(S), M.Sc(Medicinal Plants)., National Institute Siddha and Metals were authendicated by Siddha Central Research Institute, Arumbakkam and the medicine was prepared in the Gunapadam laboratory of National Institute of Siddha.
- Most of the ingredients of the drug Samuthra Pazha Nei possess anti Inflammatory, Analgesic and anti-oxidant activity.
- Biochemical Analysis (Qualitative Analysis) was done in the Biochemistry lab of National Institute of Siddha and Qualitative Analysis& Quantitative analysis was done in Sathyabama University.
- For the clinical study, 70 cases were screened and 40 cases were selected based on the Inclusion and Exclusion criteria. All the cases were treated in OPD of Ayothidoss Pandithar Hospital of NIS, Chennai.
- The clinical Trial was conducted in 40 patients of Neer Peenisam with the trial drug Samuthra Pazha Nei at the dose of 4ml twice a day with adjuvant of hot water for 48 days.
- Blood Investigation was carried out before and after treatment and data were recorded in the case report forms.
- Radiological Invastigations (X-ray for Para nasal sinuses) were also done before and after treatment.
- Clinical assessment Progress was done once in 8 days for OPD patients.
- The Pharmacological study reveals that the trial drug has Anti-inflammatory activity.

- Physico-chemical analysis, Phyto chemical analysis, Gas Chromatography withMass Spectrometry, Thin Layer Chromatography, HighPerformance Thin Layer Chromatography has also be done for trial drug.
- **Biochemical parameters:**

Absolute eosinophil count:

Out of 40 patients, 17.5% of patients had elevated absolute eosinophil count in before treatment. After treatement AEC levels of 12.5% of patients become normal and 5% of patients were moderately reduced.

- **Erythrocyte sedimentation rate:**

Out of 40 patients, after treatment ESR of 15% of patients become normal, 20 % of patients moderately reduced and 15% of patients were increased.

- **X-ray Para nasal sinuses :**

X-rays of PNS shows moderate clearance of sinuses in 25%(10 patients)

- **Clinical symptoms:**

Clinical symptoms showed 30% of patients good improvement, 50% of patients moderate improvement, 12.5% of patients mild improvement and 7.5% of patients poor improvement.

CONCLUSION

CONCLUSION

- Clinical study reveals that the trial drug showed good improvement in 30% of cases, moderate improvement in 50 cases, mild improvement in 12.5% of cases and poor improvement in 7.5% cases.
- Moderate reduction in blood parameters Absolute eosinophil count and ESR levels.
- 30 % of patients showed moderate clearance of paranasal sinuses in x-rays,
- During the course of the treatment adverse drug reactions were not found.
- The pharmacological study revealed the trial drug had Anti inflammatory activity.
- Physico chemical, phyto chemical, GCMS,TLC and HPTLC analysis showed phytoconstituents which is responsible for therapeutic action.
- Because of the encouraging clinical and laboratory results, the study may be extended with the same drug in more number of cases, in treating Neer peenisam successfully.

ANNEXURE

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI No	**CTRI/2017/03/008053** [Registered on: 09/03/2017] **Trial Registered Prospectively**
Acknowledgement Number	REF/2016/07/011810
Last Modified On:	09/03/2017
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study Clarification(s) with Reply Modification(s)	Siddha
Study Design	Single Arm Trial
Public Title of Study Clarification(s) with Reply Modification(s)	clinical evaluation of siddha drug samuthrapazha nei in the treatment of Maxillary sinusitis (Neer peenisam)
Scientific Title of Study Clarification(s) with Reply Modification(s)	Clinical Evaluation Of Siddha drug Samuthra pazha nei in the treatment Of Neer peenisam (Maxillary Sinusitis)
Acronym	
Secondary IDs if Any	**Secondary ID** / **Identifier**: NIL / NIL
Details of Principal Investigator or overall Trial	**Name**: Dr U MULLAIKARASI **Designation**: Pg Scholar **Affliation**: NATIONAL INSTITUTE OF SIDDHA

Coordinator (multi-center study) Clarification(s) with Reply Modification(s)	**Address**	Department Of Maruthuvam National Institute Of Siddha Ayothdhasar Pandithar Hospital Tambaram Sanatorium Chennai Department Of Maruthuvam National Institute Of Siddha Ayothidhasar Pandithar Hospital Tambaram Sanatorium Chennai Kancheepuram TAMIL NADU 600047 India
	Phone	9750871667
	Fax	
	Email	drmullaiamo@gmail.com
Details Contact Person Scientific Query Clarification(s) with Reply Modification(s)	**Name**	DR PERIYASAMY PANDIAN
	Designation	Associate professar
	Affliation	National institute of siddha Ayothidhasar Pandithar Hospital
	Address	Department Of Maruthuvam National Of Institute Of Siddha Ayothidhasar Pandithar Hospital Tambaram Sanatorium Chennai Department Of Maruthuvam National OF Institute Of Siddha Ayothidhasar Pandithar Hospital Tambaram Sanatorium Chennai Kancheepuram TAMIL NADU 600047 India
	Phone	9500151930
	Fax	9500151930
	Email	periasamypandian22@gmail.com
Details Contact Person Public Query Clarification(s) with Reply	**Name**	DR H VETHA MERLIN KUMARI
	Designation	Lecturer
	Affliation	National Institute Of Siddha
	Address	Department Of Maruthuvam National Institute Of Siddha Ayothidhasar

Modification(s)	

	Pandithar Hospital Tambaram Sanatorium Chennai Department Of Maruthuvam National Institute Of Siddha Ayothidhasar Pandithar Hospital Tambaram Sanatorium Chennai KANCHEEPURAM Kancheepuram TAMIL NADU 600047 India
Phone	9894782366
Fax	044-22381314
Email	dr.vetha@gmail.com

Source of Monetary or Material Support Clarification(s) with Reply Modification(s)	National Institute Of Siddha Ayothidhasar Pandithar 47 Hospital Tambaram Sanatorium Chennai

Primary Sponsor Clarification(s) with Reply Modification(s)	

Name	Ayothidhasar Pandithar Hospital
Address	National Institute Of Siddha Department Of Maruthuvam Tambaram Sanatorium Chennai 47
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor	

Name	Address
NIL	NIL

Countries of Recruitment	India
Sites of Study Clarification(s) with Reply Modification(s)	

No of Sites = **1**			
Name of Principal Investigator	**Name of Site**	**Site Address**	**Phone/Fax/Email**

	Dr U MULLAIKARASI | National Institute of Siddha | OPD NO 1 Department of Maruthuvam National Institute of siddha Tambaram Sanatorium chennai 47 Kancheepuram TAMIL NADU | 9750871667 drmullaiamo@gmail.com
Details of Ethics Committee Modification(s)	No of Ethics Committees= **1** **Name of Committee** | **Approval Status** | **Date of Approval** | **Approval Document** | **Is IEC?** INSTITUTINAL ETHICAL COMMITTEE | Approved | 26/08/2015 | Approval File | No
Regulatory Clearance Status from DCGI	**Status** | **Date** | **Aproval Document** Not Applicable | No Date Specified | No File Uploaded
Health Condition / Problems Studied	**Health Type** | **Condition** Patients | NEER PEENISAM (Maxillary sinusitis)
Intervention / Comparator Agent	**Type** | **Name** | **Details** Comparator Agent | NIL | NIL Intervention | SAMUTHRAPAZHANEI (INTERNAL) | 4 ml of samuthrapazhanei administered orally twice a day

			for a period of 48 days

Inclusion Criteria Clarification(s) with Reply Modification(s)	**Age From**	18.00 Year(s)
	Age To	50.00 Year(s)
	Gender	Both
	Details	1)18-50 years 2)Both male & female 3)The symptoms of pain in the face purulent nasal discharge and headache/heaviness of head sneezing fever tooth ache nasal block and presence of any three symptoms will be taken as inclusion criteria. 4)Patient willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48 days but can opt out of the trial of his/her own conscious discretion. 5)Patients who are willing for radiological investigation (X-ray for Paranasal sinuses) and provide blood urine for lab investigation.

Exclusion Criteria	**Details**	1) Bronchial asthma 2)Tuberculosis 3)Diabetes mellitus 4)Hypertension

	5)Pregnancy and lactation 6)Heart disease 7)Chronic obstructive pulmonary disease
Method of Generating Random Sequence	Not Applicable
Method of Concealment	Case Record Numbers
Blinding/Masking	Open Label
Primary Outcome Clarification(s) with Reply Modification(s)	**Outcome** / **TimePoints** Outcome is mainly assessed by laboratory and clinical symptom scoring. / 48 days
Secondary Outcome Clarification(s) with Reply Modification(s)	**Outcome** / **TimePoints** Secondary outcome will be assesed by comparing the following parameters pre and post treatment. Influence of other co factors related to the disease such as age sex etc. Changes in other investigation like DC ESR AEC etc / 48 days
Target Sample Size	**Total Sample Size=**"40" **Sample Size from India=**"40"
Phase of Trial	Phase 3
Date of First Enrollment (India) Clarification(s) with Reply Modification(s)	15/03/2017

Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**"0" **Months=**"6" **Days=**"0"
Recruitment Status of Trial (Global) Clarification(s) with Reply Modification(s)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NONE YET
Brief Summary Clarification(s) with Reply Modification(s)	It is a single non- randomized, open- label trial to determine the efficacy of SAMUTHRAPAZHA NEI (prepared from herbal and mineral constituents such as Barringtonia acuteangula(dry fruit), Zingiber officinale, Allium sativum, Root of moringa oleifera, Root of Plumbago zeylanica, Carum copticum,Sodium chloride (rock salt), Zingiber officinale(dry ginger),Piper nigrum, Piper longum, Root of piper longum(seviyam), Ammonium chloride(navacharam), Nigella sativum,Cuminum cyminum, Cissus quadrangularis and ghee) in patients with Neer peenisam(MAXILLARY SINUSITIS). In this trial 40 patients will be recruited and the trial drug will be administered 4 ml twice a day for a period of 48 days.During the trial period if any AE/SAE/SUSAR will be noticed and referred to pharmacovigilance dept in NIS and further management will also be given in NIS OPD/IPD. The entire trial will be monitored by the research monitoring committee of NIS. During this trial all the safety efficacy parameters will be recorded in the CRF .After completion of the trial all the study related data will be analysed statistically. The outcome of this trial will be published in Indian journal of Medical Research.

NATIONAL INSTITUTE OF SIDDHA
राष्ट्रीय सिद्ध संस्थान
Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE
आयुष विभाग - स्वास्थ एवं परिवार कल्याण मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियम चेन्नई -600 047
फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16 Dt: 05.10.2015

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.U.Mullaikarasi, Department of Maruthuvam	
Protocol title: A Clinical study on SAMUTHRAPAZHA NEI in the treatment of NEER PEENISAM.	
Documents filed	1) Protocol, 2) Data Collection forms 3) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	Yes
Informed consent documents	Yes
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/9/2014-15/4 – 26.08.2015**

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

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

Chairman

Member Secretary

சித்த மருத்துவ மைய அராய்ச்சி நிலையம், சென்னை — 600 106
सिद्ध केंद्रीय अनुसन्धान संस्थान, अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई - 600106
SIDDHA CENTRAL RESEACH INSTITUTE
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai – 600106
Phone: 044-2621 4925, Fax: 044-2621 4809
www.crisiddha.tn.nic.in, Email: crisiddha@gmail.com

25.05.2016

CERTIFICATE

Certified that the samples submitted for identification by Dr. V. Mullaikarasi, II year MD Student, Department of Maruthuvam, National Institute of Siddha, Chennai-600 047 are identified as Navacharam – Ammonium chloride and Inthuppu – Sodium chloride (Impure).

(R. Shakila)
Research Officer (Chemistry)

(Dr. P. Sathiyarajeswaran)
Assistant Director (Scientist 2) I/c
सहायक निदेशक निदेशक Asst.Director I/c
सिद्ध केंद्रीय अनुसंधान संस्थान
Siddha Central Research Institute
अरुम्बाक्कम, चेन्नई-600106
Arumbakkam, Chennai - 600106

The Tamil Nadu Dr.M.G.R.Medical University

69,Anna Salai,Guindy,Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....U. Mullaikarasi.....

for participating as ~~Resource~~ ~~Person~~ / Delegate in the Eighteenth Workshop on

" RESEARCH METHODOLOGY & BIOSTATISTICS "

FOR AYUSH POST GRADUATES & RESEARCHERS

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 20 th to 24 th July 2015.

Dr.N.KABILAN, M.D.(Siddha)
READER,DEPT.OF SIDDHA

Prof. **Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.D.SHANTHARAM,** M.D., D.Diab.,
VICE - CHANCELLOR

Noble research solutions
We Trust in Quality and Ethics

Noble Research Solutions

We Trust in Quality and Ethics

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Date: 23.03.2017

To,

Dr.U.Mullaikarasi
National Institute of Siddha
Tambaram Sanatorium, Chennai - 600 047, Tamil Nadu, India.

Project Id: NRS/AS/0024/02/2017

This is to certify that the trial drug *Samuthra Pazha Nei* formulated by Dr.U.Mullaikarasi from National Institute of Siddha, Chennai, was analyzed for the following activity at our facility.

S.No	Study Description	Annexure no
1.	Standardization and Physicochemical Evaluation of study drug *Samuthra Pazha Nei (SPO)*	I
2.	Evaluation of In-Vitro anti-Inflammatory Activity of *Samuthra Pazha Nei (SPO)* by Protein (Albumin) denaturation Assay	II

Note:

- *Annexures was attached as a separate enclosure along with this report.*

NOBLE RESEARCH SOLUTIONS TAMIL NADU INDIA CHENNAI

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDASAR PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

CLINICAL EVALUATION OF **"SAMUTHRAPAZHA NEI"** IN THE TREATMENT OF **NEER PEENISAM"** (MAXILLARY SINUSITIS).

FORM I SCREENING & SELECTION PROFORMA

REG NO:

1. STUDY NO_____ **2. OP /IP NO:_____**

3. NAME :_____ **4. AGE/SEX_____**

5. RELIGION: H / C / M / O **6. OCCUPATION & INCOME:**

_

7. CONTACT NO:

INCLUSION CRITERIA:

* Facial pain, purulent nasal discharge, nasal block, headache/ heaviness of head, sneezing, fever, tooth pain.
* Age 18 to 50yrs Yes/No
* Sex Male/Female
* Patient willing to under go lab investigations Yes/No
* Patient willingness for consent to include in the trial Yes/No
* Patient willingness for radiological investigation(x ray of paranasal sinuses). Yes/No

EXCLUSION CRITERIA:

Bronchial asthma	Yes/No
Tuberculosis	Yes/No
Diabetes mellitus	Yes/No
Hypertension	Yes/No
Heart disease	Yes/No
Chronic obstructive pulmonary disease	Yes/No
Pregnancy & lactation	Yes/No

ADMITTED TO TRAIL: YES ☐ NO ☐ If Yes Serial NO:

Date:
Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDASAR PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

CLINICAL EVALUATION OF **"SAMUTHRAPAZHA NEI"** IN THE TREATMENT OF **NEER PEENISAM"** (MAXILLARY SINUSITIS).

FORM II-CASE RECORD FORM

IEC NO:

1. Serial No of the patient: _____
OP.NO/IP.NO:_____

2. Name: _____ 3. Gender: F/M

4. Age (years): _____ DOB ☐☐ ☐☐ ☐☐☐☐

5. Address:
_____

6. Occupation: _____

7. Educational Status: A) Illiterate ☐ B) Literate ☐

8. Height:_____cm 9.Weight:_____kg 10. BMI: _____ kg/m²

11. Marital status: 1.Married ☐ 2.Unmarried ☐

10. **Complaints and Duration:**
_____
_____
_____
_____

11. **History of present illness:**
_____
_____
_____
_____

12. **Past History:**
_____
_____
_____
_____

13. **Socio economic status:**

Income group 1.lower ☐ 2.middle ☐ 3.higher ☐

14. **Treatment History:**

Had the patient been treated before with Allopathy drug? Yes ☐ No ☐

15. Family history:

Whether Allergic rhinitis, Bronchial asthma, Allergic dermatitis runs in family?

1) Yes ☐ 2) No ☐

If yes, mention the relationship of affected person(s)

1. _____
2. _____
3. _____

16. Habit of

A) Smoking 1. Yes; duration _____ years; 2.No

B) Tobacco chewing 1. Yes; duration _____ years 2.No

C) Betel chewing 1. Yes; duration _____ years 2.No

D) Alcoholism 1. Yes; duration _____ years; 2.No

17. Dietry style: A) Pure vegetarian B) Non-vegetarian C) mixed diet

SIDDHA SYSTEM OF EXAMINATION:

1. ENVAGAI THERVU: [EIGHT-FOLD EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

NAADI	BEFORE TMT	AFTER TMT	NAADI	BEFORE TMT	AFTER TMT
Vali			Iyya vali		
Azhal			Vali Iyyam		
Iyyam			Azhal Iyyam		
Vali Azhal			Iyya Azhal		
Azhal vali					

II. NAA:[TONGUE]

	BEFORE TMT	AFTER TMT
Colour	Dark/Yellow/Red / Pale/Normal	Dark/Yellow/Red/Pale/Normal
Taste	Sweet/Bitter/Sour Pungent/None	Sweet/Bitter/Sour Pungent/None
Coating	Present/Absent	Present/Absent
Fissure	Present/Absent	Present/Absent
Saliva	Normal/Increased/Decreased	Normal/IncreasedDecreased
Dryness	Present/Absent	Present/Absent
Glossitis	Present/Absent	Present/Absent
Baldness	Present/Absent	Present/Absent

III.NIRAM: [COMPLEXION]

BEFORE TMT	AFTER TMT
Dark/Yellow tinted/ Wheatish brown / Pale	Dark/Yellow tinted / Wheatish brown/ Pale

IV.MOZHI: [VOICE]

BEFORE TMT	AFTER TMT
Medium/High/Low pitched	Medium/High/Low pitched

V.VIZHI: [EYES] (Lower palpabrel conjunctiva)

BEFORE TMT	AFTER TMT
Yellow Red/ Pale/Normal	Yellow Red/ Pale/Normal

VI. MALAM; [BOWEL HABITS / STOOLS]

Malam	BEFORE TMT	AFTER TMT
Colour	Dark/ Yellow/Pale/Others	Dark/ Yellow/Pale/Others
Consistency	Solid/Semisolid/Watery	Solid/Semisolid/Watery
Stool bulk	Normal/Reduced	Normal/Reduced
Constipation	Present/Absent	Present/Absent
Diarrhoea	Present/Absent	Present/Absent

VII. URINE EXAMINATION:

NEERKURI	BEFORE TMT	AFTER TMT
Niram [Colour]	White/Yellowish/Straw coloured/ Crystal clear	White/Yellowish/ Straw coloured/ Crystal clear
Manam [Odour]	Present/ Absent	Present/ Absent
Nurai [Froth]	Nil/ Reduced/ Increased	Nil/ Reduced/ Increased
Edai [Sp.gra]	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced
Enjal [Deposits]	Present/ Absent	Present/ Absent
Volume	Normal/ Increased/ Reduced	Normal/ Increased/ Reduced

NEIKURI	BEFORE TMT	AFTER TMT
Serpentine fashion		
Annular/Ringed fashion		
Pearl beaded fashion		

Mixed fashion		
Other fashion		

VIII. SPARISAM: [PALPATORY PERCEPTION]

BEFORE TMT	**AFTER TMT**
Warm/Cold/Normal/ Sweat	Warm/ Cold/Normal/Sweat

5. THEGI: [TYPE OF BODY CONSTITUTION]

Vatham predominant		Kabam predominant	
Pitham predominant		Thondha udal	

6. NILAM: [LAND WHERE PATIENT LIVED MOST]

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Palai ☐

7. KAALAM

Kaarkalam	☐	Pinpanikalam	☐
Koothirkalam	☐	Ilavenil	☐
Munpanikalam	☐	Muthuvenil	☐

8. GUNAM

Sathuvam ☐ Rasatham ☐ Thamasam ☐

9. AIYMPORIGAL (SENSORY ORGANS)

IYMPORIGAL	BEFORE TMT	AFTER TMT
Mei (Skin)		
Vai (Buccal Cavity)		
Kann (Eye)		
Mooku (Nose)		
Sevi (Ear)		

10. KANMENDRIYAM (MOTOR ORGANS)

KNMENDRYAM	BEFORE TMT	AFTER TMT
Kai (upper limb)		
Kaal (lower limbs)		
Vai (buccal cavity)		
Eruvai (excretory organs)		
Karuvai (reproductive organs)		

11. KOSANGAL (Sheath)

KOSANGAL	BEFORE TMT	AFTER TMT
Annamaya Kosam		
Pranamaya kosam		
Manomaya kosam		
Vignanamaya kosam		
Ananthamaya kosam		

12. MUKKUTRAM: [AFFECTION OF THREE HUMORS]

A) VATHAM:

VATHAM	BEFORE TMT	AFTER TMT
Praanan		
Abaanan		
Samaanan		
Udhaanan		
Viyaanan		
Naagan		

Koorman		
Kirukaran		
Devathathan		
Dhananjeyan		

B) PITHAM:

PITHAM	BEFORE TMT	AFTER TMT
Anarpitham		
Prasakam		
Ranjakam		
Aalosakam		
Saathakam		

C) KABAM:

KABAM	BEFORE TMT	AFTER TMT
Avalambagam		
Kilethagam		
Pothagam		
Tharpagam		
Santhigam		

13. SEVEN DHATHUS: (7 SOMATIC COMPONENTS)

	BEFORE TMT	AFTER TMT
Saaram [Chyme]		
Senneer [Blood]		
Oon [Muscle]		

Kozhuppu [Fat]		
Enbu [Bones]		
Moolai [Bonemarrow]		
Sukkilam/Suronitham		

14. GENERAL EXAMINATION:

GENERAL EXAMINATION	BEFORE TMT	AFTER TMT
Height (cm)		
Weight (kg)		
Temperature(°F)		
Pulse rate (per min)		
Heart rate (per min)		
Respiratory rate (per min)		
Blood pressure(mm/Hg)		
Pallor		
Jaundice		
Cyanosis		
Lymphadenopathy		
Pedal Oedema		
Clubbing		
Jugular venous pulsation		

15. SYSTEMIC EXAMINATION:

SYSTEMIC EXAMINATION	BEFORE TMT	AFTER TMT
LOCOMOTOR SYSTEM		
CARDIO VASCULAR SYSTEM		
RESPIRATORY SYSTEM		
GASTRO INTESTINAL SYSTEM		
CENTRAL NERVOUS SYSTEM		
UROGENITAL SYSTEM		
ENDOCRINE SYSTEM		

16. CLINICAL SYMPTOMS

1	Rhinorrhoea	**0** **1** **2** **3**
2	Nasal obstruction	**0** **1** **2** **3**
3	Sneezing	**0** **1** **2** **3**
4	Headache/ Facial pain	**0** **1** **2** **3**
5	Post nasal dripping	**0** **1** **2** **3**

0 = Nil

1 = mild

2 = moderate

3 = severe

DATE:

STATION:

SIGNATURE OF THE INVESTIGATOR

SIGNATURE OF THE LECTURER **SIGNATURE OF THE HOD**

NATIONAL INSTITUTE OF SIDDHA,CHENNAI – 47

AYOTHIDASAR PANDITHAR HOSPITAL

DEPARTMENT OF MARUTHUVAM

CLINICAL EVALUATION OF **"SAMUTHRAPAZHA NEI"** IN THE TREATMENT OF **NEER PEENISAM"** (MAXILLARY SINUSITIS).

FORM III LABORATORY PARAMETERS-CHART

1. OP/IP No: _____ 2.S.No:_____ 3.Reg no:

4.Name: _____ 5.Age/Sex:_____

BLOOD INVESTIGATION		NORMAL VALUES	BEFORE TMT	AFTER TMT
HB(gms%)		M:13-18 W:11-16		
T.RBC(million cells /cu.mm)		M:4.5-6.5 W:3.5-5.5		
ESR (mm)	½ hr.	M:0-10 W:0-20		
	1 hr.			
T.WBC (cells /cu.mm)		4000-11000		
DIFFERENTIAL COUNT (%)	Polymorphs	40-75		
	Lymphocytes	20-35		
	Monocytes	2-10		
	Esonophils	1-6		
	Basophils	0-1		

Blood Investigation		Normal Values	BeforeTMTDate:	AfterTMTDate
Blood glucose (mg/dl)	Fasting	70-110mg/dl		
	PP	80-140mg/dl		

Specific investigation	Before TMTDate:	After TMTDate:
X ray of Para nasal sinus		
Absolute esinophil [40-440 cells/cu.mm)]		

URINE INVESTIGATION	Before TMT(with Date)	After TMT (With Date)
Albumin		
Fasting sugar		
PP sugar		
Deposite		
Bile salts		
Bile pigments		

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDASAR PANDITHAR HOSPITAL
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CLINICAL EVALUATION OF **"SAMUTHRAPAZHA NEI"** IN THE TREATMENT OF **NEER PEENISAM"** (MAXILLARY SINUSITIS).

FORM IV – (DRUG COMPLIANCE FORM)

Name:_____ OP/IP No: Serial No: DRUG NAME: _____

DOSE:_____ (After food)

On 0th day -Date: Drugs issued: Drugs returned:

On 8th day -Date: Drugs issued: Drugs returned:

On 16th day -Date: Drugs issued: Drugs returned:

On 24thday -Date: Drugs issued: Drugs returned:

On 32th day -Date: Drugs issued: Drugs returned:

On 40th day -Date: Drugs issued: Drugs returned:

On 48th day -Date: Drugs issued: Drugs returned:

Day	Date	Morning (7-8 am)	Evening (7-8 pm)
Day 1			
Day2			
Day3			
Day4			
Day5			
Day6			
Day7			
Day8			
Day9			
Day10			
Day11			
Day12			
Day13			
Day14			
Day15			
Day16			
Day17			
Day18			

Day19			
Day20			
Day 21			
Day22			
Day23			
Day24			
Day 25			
Day 26			
Day27			
Day 28			
Day29			
Day30			
Day31			
Day32			
Day33			
Day34			
Day35			
Day36			
Day37			
Day38			
Day39			
Day40			
Day41			
Day42			
Day43			
Day44			
Day45			
Day46			
Day47			
Day48			

DATE:

STATION:

SIGNATURE OF THE INVESTIGATOR

SIGNATURE OF THE LECTURER **SIGNATURE OF THE HOD**

தேசிய சித்த மருத்துவ நிறுவனம், சென்னை- 47

அயோத்திதாசர் பண்டிதர் மருத்துவமனை

நீர் பீனிசம்**நோய்க்கான சித்த** மருந்தின் ("சமுத்திரபழ நெய்")**பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான ஒப்புதல் படிவம்**

FORM VI ஒப்புதல் படிவம்

நான் மேற்கூறிய தகவல் படிவத்தை படித்து அல்லது படிக்க கேட்டுக் கொண்டேன்.அது தொடர்பான விளக்கங்களையும் கேட்டு தெரிந்துகொண்டேன்.எந்த வித வற்புறுத்தலின்றி என் சொந்த விருப்பத்தின் பேரில் என்னை இந்த ஆராய்ச்சிக்கு உட்படுத்த என் முழுமனதோடும் சுயநினைவோடும் சம்மதம் தெரிவிக்கின்றேன். எனக்கு விருப்பம் இல்லாத பட்சத்தில் இந்த ஆராய்ச்சியில் இருந்து என்னை எப்போது வேண்டுமானாலும் விடுவித்து கொள்ளும் உரிமையை பெற்றுள்ளேன் என்பதையும் அறிவேன்

தேதி :

இடம் :

சாட்சிக்காரர்

கையொப்பம்

கையொப்பம்

பெயர்

பெயர்

உறவுமுறை:

மருத்துவர் கையொப்பம்:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDASAR PANDITHAR HOSPITAL

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FORM VICERTIFICATE OF CONSENT

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

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

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

Date:

Signature of the participant

In case of illiterate participant,\

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

Date:

Signature of a witness

Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDASARPANDITHARHOSPITAL

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CLINICAL EVALUATION OF "SAMUTHRAPAZHA NEI" IN THE TREATMENT OF NEER PEENISAM" (MAXILLARY SINUSITIS).

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

Reg No:

Serial No: OP/IP No:

Name: Age: Gender: M/F

DATE OF TRIAL COMMENCEMENT:

DATE OF WITHDRAWAL FROM TRIAL:

REASONS FOR WITHDRAWAL:

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

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Reporting Form for Suspected Adverse Reactions to Siddha Drugs

Date of trial commencement:

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.

PeripheralCenter code: State:

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

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

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

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

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

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

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

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

b) Dietary Restrictions if any

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

d) Any other relevant information.

5. Treatment provided for adverse reaction:

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

<table>
<tr><td>Recovered:</td><td>Not recovered:</td><td>Unknown:</td><td>Fatal:</td><td>If Fatal

Date of death:</td></tr>
<tr><td rowspan="2">Severe: Yes / No.</td><td colspan="4">Reaction abated after drug stopped or dose reduced:</td></tr>
<tr><td colspan="4">Reaction reappeared after re introduction:</td></tr>
</table>

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,

ntre For Siddha Medicine),

Tambaram Sanatorium, Chennai-600 047.

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,

Confidentiality

⇒ The patient's identity will be held in strict confidence and protected to the fullest extent

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47

AYOTHIDASAR PANDITHAR HOSPITAL

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FORM VIII DIETARY ADVICE FORM

சேர்க்க வேண்டிய உணவுகள்	**சேர்க்க கூடாதவைகள்**
காய்கறிகள்: முருங்கை,கருணை, கத்திரிபிஞ்சு, தக்காளிகேரட், இஞ்சி, பூண்டு,பச்சைக்காய்கறிகள். **பழங்கள்:** ஆரஞ்சு, அன்னாசி,எலுமிச்சை, ஆப்பிள், பப்பாளி, கொய்யா, பேரீச்சை, கற்பூரவள்ளி, செவ்வாழை, மாம்பழம் **கீரைகள்:** கரிசாலை, மணித்தக்காளி,முருங்கை, **பருப்புவகைகள்** வரப்புநண்டு, வேகவைத்த மீன், மிளகு சேர்த்த முட்டை. **சூப்வகைகள்:** நண்டு, ஆட்டுக்கால், காய்கறி, கொதிக்கவைத்தாறிய வெந்நீர் இஞ்சி, சுக்கு சேர்ந்த காபி, மஞ்சள், மிளகு சேர்ந்த பால், ஆவியில் வேகவைத்த பண்டங்கள் (இட்லி, இடியாப்பம், புட்டு, ஆப்பம்) புழுங்கலரிசி சாதம், பாசிப்பருப்பு சாம்பார், மிளகு ரசம்,தூதுவேளை துவையல், முசுமுசுக்கை அடை **வேது**: (ஆவிபிடித்தல்) துளசி, மஞ்சள், சுக்கு ,எலுமிச்சை இலை	* குளிர்பானங்கள்(சாக்லேட், கேக்) * புகை, தூசு குளிர்ந்த காற்**று,** பனி * கோழிக்கறி, பதப்படுத்தப்பட்ட உணவுகள் * காளான், தயிர், ஊறுகாய் * மக்காச்சோளம் * இனிப்பு, புளிப்பு பண்டங்கள் * கிழங்கு வகைகள், அகத்திகீரை வெள்ளரி, பாகல். * சுரைக்காய், பூசணிக்காய், பீர்க்கு, புடலை * வெற்றிலை, பாக்கு, புகையிலை * மதுஅருந்துதல் * பழைய தலையனை

BIBILIOGRAPHY

1. "Aathi Siddha Maruthuvam Enra Aathmaratchaamirthamennum Vaithiya Saara Sangiragam" First edition - 2011, (page no: 517)

2. N.Kandasamy pilli, History of siddha medicine 2nd edition, pg no 853.

3. K.S.Utthamarayan, Siddhar aruvai maruthuvam 4th edition, pg no 172.

4. Dr.M.Shanmugavelu, noi nadal noi mudhal nadal, 2nd edition, part 2, pg no 86.

5. Praveen kumar, Nichael Clark, Clinical medicine 5th edition, pg no 153.

6. Dr.M.Shanmugavelu, noi nadal noi mudhal nadal part 2, pg no 83.

7. Lucal.TW.Schiller j.Benson v summary health Statistics for us adult, national health interview survey 2001.

8. Ray, NF.Baraniok JN.Tlamer m.Rhinlart c.s uergen pt.kalliner m.et.al Healthcare expenditures for sinusitis in 1996.

9. Nadkarni, Indian materica medica 3rd edition, vol, pg no 1308.

10. K.Vasuthava sastri,S.venketrajan, Sarabenderar vaidhya muraikal.[It is stated under seeroroga chikchai] 3rd edition ,pg no 39.

11. C.Kannusamy pilli, Patharthaguna vilakkam, edition in 2006, pg no71.

12. C.Kannusamy Pilli, Sigicha rathna deepam, edition 2007, pg no 28.

13. Siddha maruthu vaanga surukam.

14. Gunapadam mooligai by Murugesa muthaliyar.

15. Udal thathuvam by N.M.Venugopal.

16. Yugi vaithya chinthamani 800, by S.P. Namachandran.

17. Agasthiyar Kanma Kandam kowmathi nool -300

18. Pathinen siddhar naadi saasthiram and Guru naadi.

19. Jeeva ratchamirtahm.

20. T.V.Sambasivam pillai maruthuva agarathi.

21. Agasthiyar 2000.

22. Thanvanthiri vaithyam.

23. Patharthaguna chinthamani by S.K.Namachandran.

24. Sarabendrar vaithyamurai, siraroga sigichai 3rd edition.

25. The international journal of pharmacology ISSN.

26. Theriayar sekarapa.

27. Agasthiyar gunavagdam.

28. Text book of ear, Nose, Throat. Lt.col.B.S.Tuli.

29. The journal of allergy and clinical Immunology, vol-127, Issue 3 March 2011.

30. Reviews on Indian Medicinal plamts , vol-4, Indian Council of Medical Research , New Delhi-2004.

31. Vijayverma, International Encyclopedia of Medicinal plants, Ammol publications pvt, limited, New Delhi.

32. Kirtikar KR, Basu BD, Indian medicinal plants-vol 5, Sri satguru publications, New Delhi.

33. Madhu sharma, Neeraj tendon & Gupta, Reviews on Indian Medicinal Plants, Indian council of Medical Research, New Delhi.