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CHENNAI – 600 032

A STUDY ON

VIRANA SILETHUMAM

(DISSESSATION SUBJECT)

For the partial fulfillment of the

Requirements to the Degree of

DOCTOR OF MEDICINE (SIDDHA)

BRANCH IV – DEPARTMENT OF KUZHANTHAI
MARUTHUVAM

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1. INTRODUCTION

Siddha system of medicine has virtually classified diseases into 4448 types on
basis of the three humours ie, Vatham, Pitham, Kabam constituting the fundamentals of
this system. According to Classical Siddha literatures derangement of kabam can lead to
21 different types of illnesses, of which Virana Silathamam is one of the disease.

The clinical picture of virana silathamam includes sore throat with mucous and
pustular exudates, swelling of anterior and posterior cervical area with fever, rigor,
burning sensation all over the body, cough, crying out of severity, ulceration of throat and
tongue. The symptomatology of Virana Silathamam may be comparable with that of
Acute Pharyngo-tonsillitis.

Around the world sore throat is one of the very common recurrent illnesses in
children of which 37% being diagnosed as acute bacterial Pharyngo-tonsillitis\(^1\). It is a
common condition nearly all children are becoming infected atleast once. Indian children
are more prone to the risk of developing complications like rheumatic fever, acute
glomerulonephritis due to the prevailing unhygienic conditions. About 80% of children
with obstructive sleep apnoea are suffering from tonsillar hypertrophy\(^2\).

The initial management for infected tonsils in allopathic medicine is antibiotics. If
frequent infections or trouble breathing occur tonsillectomy will be done. Administration
of antibiotics and analgesics to children have resulted in the development of higher
resistance recurrences, Reye’s syndrome, etc (Arora \textit{et al}, 1999) and also kill healthy
intestinal bacteria which helps to keep the immune system healthy.

Around 200,000 tonsillectomies are done annually in India which is the
commonest surgical procedure in children. Tonsillectomy also has demerits children like
post-operative haemorrhage, pain, nausea, vomiting etc..
This compels me to explore an efficacious anti-microbial drug which is purely herbal, adequately safe and easily available for pediatric population. The constituents of trial drug Coriandrum sativum, Cuminum cyminum, Nigella sativa possess antibacterial activity. Glycyrhiza glabra possess anti-inflammatory and anti-allergic activity. Also the drug has essential oil containing predominantly derivative of Eugenol (Hattori et al 1986), which act potently against 25 genera of bacteria (including Streptococcus, B.subtilis), some of which are involved in causing pharyngo tonsillitis (Ghelardini et al 2007).

In our research, we have studied the clinical efficacy of the experimental formulation in children. The above said formulation ingredients are herbal origin only. Even though the drugs are pure herb, we have studied preclinical safety study. It shows that the formulation has potential anti-inflammatory activity clinically effective in the management of Virana Silethumam.
2. AIM & OBJECTIVES

AIM

- To study the efficacy of Malli chooranam for the management of Virana silethumam with reduction of clinical symptoms.
- To ensure a combined approach of modern and siddha concepts for the clinical diagnosis of the Virana silethumam.

OBJECTIVES

- To evaluate the Safety of *Malli Chooranam* by Acute and Sub acute Toxicity studies in animal models.
- To evaluate the Safety and Efficacy of *Malli Chooranam* in pediatric population.
- To study the subjective changes of
  - Udal kattugal,
  - Ennvagai Thervu and
  - Mukkutram in patients with Virana silethumam.
- To elucidate the correlative aspects of Virana silethumam and Acute Pharyngo-tonsillitis in terms of clinical manifestations.
3. REVIEW OF LITERATURE

SIDDHA ASPECTS

The term Virana silethumam, etiology and clinical manifestations is briefed in *Siddha maruthuvam- Pothu* text. Information regarding various features was collected from other Siddha literatures.

**தம்மு (DEFINITION):**

Accumulation of phlegm in the throat, chest leads to derangement of kabam, pitham in areas of throat, nose, tonsil producing inflammation and exudation of mucus, phlegmatic secretions from these regions.

**சொற்று வருவன (SYNONYMS):**

- Thondai Kuru
- Thondai Kattu
- Thondai Kabam
- Thondai Kirandhi veekam
- Thondail Valarum sathai
- Kural Kammal
- Kala Biruntham
- Kala Vanguram
- Kala Chundi
- Kanda Kiranthi
- Kanda Santhu rogam
- Kanda Salugam
- Kanda Sundi
ETIOLOGY:

Exposure to cold air, excessive eating, frequent intake of sweet and sour taste foods, tubers, previously cooked rice and climatic extremes in the month of masi, panguni will lead to excessive accumulation of Iyam.

According to Pillai Pini maruthuvam, accumulation of Kabam in children’s throat is caused by

- Poor health condition of mother
- Playing in cold water,
- Frequent eating of cold food items,
- Exposure to cold air,
- Poor nutritional condition of the child.

In Kuzhandaigal noigal part-V, it is said that kabam condensed in areas of head, throat, and chest gets dried further spreading in fluid nature throughout the body

Due to inattentive parental care, concerning actions of child there can be an exacerbation of the phlegm in the chest and others regions.
Previous karmic deeds, thosham of the organs, excessive water in regions of head, ill mother’s milk, and affliction of child’s nerves leads to accumulation of phlegm in children as told in the above poem taken from *Kuzhandaigal noigal part-V*.

(CLASSIFICATION):

According to *Siddha Maruthuvam Pothu*, there are 21 types of Silethumam ailments and Virana silethumam is one among them.
The 21 types of Silethumam are as follows:


**PATHO-PHYSIOLOGY:**

Head, throat, chest, nose, tongue, rasa thathu are main sites of Kapham. It is responsible for the secretory and lubricatory functions of these organs. The chemical changes that takes place alongside; underline the synergy of pitham in maintaining healthy secretory mucosal lining of the sites of kapham. *(Siddha Maruthuva Sudar)*

The etiological factors ("Silettuma malam" in *TV.Sambasivam pillai Dictionary*) cause

1. Derangement of Kapham in first place followed by
2. Derangement of Pitham producing an inflammatory reaction of the lining secretory mucosa.
3. Inorder to excrete the exudative secretions produced, body initiates a sequelae of response leading to morbid condition, Virana Silethumam.
According to the above poem in *Siddha maruthuvam-pothu*, the clinical manifestations are as follows:

- Ulceration of throat with exudation of mucosal, pustular exudates
- Swelling in neck, nape of neck and cheek accompanied by fever, rigor
- Burning sensation in the body
- Cough, crying out of severity of pain
- Ulcerations of throat and tongue.

Siddha terminologies specifically related to & in support of Virana silethumam was found to be in *Tamil-English Dictionary by TV.Sambasivampillai*. They are,

- Silettuma vali: body ache caused by deranged kapham
- Sileshma thalaivali: A kind of headache in which the palate and the throat secretion to be covered with a coat of sticky mucus with a feeling of cold and heaviness of head, which cannot be turned about.
- Kanda suram: fever caused by deranged kapham.
- Kanda sosham: dryness of throat
- Kanda soolai: pricking pain in throat due to disease of throat glands.
- Kanda peedam: sharp/acute pain in the throat.
Since infants and young children may not be correctly able to explain symptoms, diagnosis of diseases depend upon the sharp analytical capability of physician. According to *BalaRoga nithaanam, Kashyaba samhitai*, mild rise in temperature, distaste, excessive salivation, inability to swallow it may be enough in diagnosing a throat disease.

Piniyari muraimai – The method of diagnosing in Siddha is based upon

1. Poriyal arithal (Physician’s use of sense organs in examining the affected parts of the patients)
2. Pulanal arithal (Physician’s use of the five sense in apprehending the disease).
3. Vinathal (asking informations regarding the history of the disease, its clinical feature etc., from the patient or his close relatives who are taking care of him).
4. Ennvagai thervugal (eight fold examination).

The above principles correspond to the methodology of

(a) Inspection, (b) Palpation and (c) Interrogation as in modern medicine.

In Siddha, among the 10 types of “alavaigal” (analytical tools), first three are very significant and useful in examination of a patient. They are,

1. Kaandal: (Inspection by Siddha method)
2. Karuthal: (Through Siddha Investigations)
3. Urai: (Literature reference of Siddha system)
This is an important part of diagnosis as framed by siddhars. This includes,

1. **Sensation to touch**: Sparisam is a method of palpation and percussion to know the condition of the body like warm, fever, chillness, sweating, numbness, paresthesia, dryness of the body, erosion patches, ulcers, edema, emaciation, swelling, obesity and enlargement of liver, spleen.

   In Virana silethumam, there is
   - Swelling in the cervical region
   - Warmth in areas of swelling
   - Pain in the areas of swelling
   - Fever
   - Dryness of skin
2. உயர்வு (Tongue) :

This is the method of inspection of the tongue mainly gums, teeth, lips, palate etc. In Virana silethumam,
- Whitish nature of the tongue with coating and pallor was observed indicating the derangement of Silethumam.
- Soreness at the edges of the tongue during fever indicating aggravation of pitham.

3. நிறம் (Colour) :

Colour (indicating the vatham, pitham, kabam, mukkutram) yellow, pallor, redness of the skin and colour of nail beds are noted. In Virana silethumam, pallor of skin will be present as it is one of the kabam ailments.

4. வெருமை (Voice):

Clarity of voice, any disturbances in speech, loud voice, slurring, crying, talk induced by hallucination are noted. In Virana silethumam, voice disturbances are due to sore throat and hoarseness of voice. Difficulty in speaking is due to excessive pain in swallowing the saliva.

5. கண்காட்டு (Eyes) :

Abnormal colour changes indicate the three thodams. Pallor, excessive lacrimation, accumulation of secretion at the angle of eyes, subconjunctival bleeding, and any specific diseases in the eyes are noted. In Virana silethumam, pallor of conjunctivae is present. In few, there is diffuse congestion of the conjunctivae due to continuous cough.
6. Faeces:

The following are noted:

- Quantity, colour, odour, frothy, consistency, indigestion, frequency are noted.

Few patients had reduced frequency of defecation and passing of hard stools.

7. Urine:

The following are observed:

1. Niram - Colouration
2. Edai - Specific gravity
3. Manam - Smell
4. Nurai - Frothy Nature
5. Enjal - Quantity of urine voided.
The diagnosis and prognosis of Muthodam, derangement of the disease are studied on the basis of behaviour by drop of gingelly oil on the surface of the urine kept in a wide vessel in the sunlight.

The collected specimen as said above is to be analyzed by following method. The specimen is kept open in a glass dish. It is to be examined under direct sunlight, without any shaking of the vessel. Then add on drop of gingelly oil by at distance of ½ or ¾ height, observe keenly the direction in which it spreads within few minutes, and conclude the diagnosis as follows,

"அருளம் சிறுத்தை அல்லது பாத்திராம்பக் கிடைக்கும் பொழுது பொச்சை விளைந்து  பொருத்திய பொருள்

பருக்கின்ற வருடக்காலம் பருக்கின்ற வருடக்காலம்

பக்தகினி நெடுக்கும் பாலனின் பால்

பக்தகினி நெடுக்கும் பாலன் நெடுக்கும் பால்

சுவை சுவை பிள்ளையாளருள் பால்

சுவையுடைய பாலக்கு பால் சுவையுடைய பால்

சுவை பாலக்கு பால்சுவை பிள்ளையாளருள் காட்டியே.

-சுவையுடைய சுவை பாலக்கு 600"
Naadi is a suitable diagnostic tool used by siddhars from the unknown past. It can be felt one inch proximal to the wrist on the radial side by means of palpation with the tip of index, middle and ring fingers corresponding vatham, pitham and Kabam respectively. The three humours Vatham, Pitham and Kabam exits in the ratio 1:1/2:1/4 normally.

Any derangement in the ratio produces disease as in *Thirukural*,

"நீதியால் கருப்பிதம் விரும்பு விருப்பு மக்கில் காணும் வட்டியில் குறுப்பு ".

Examination of the Naadi has been recognized as one of the principle means of diagnosis. But Naadi is not much used for the pediatric diagnosis because considering the physical conditions of the child; naadi can not be understood correctly in children. It is stressed by *Siddha maruthuva chudar* following *Sathaga naadi* verse,

"நீதியால் கருப்பிதம் விரும்பு விருப்பு 
செய்லில் பிடிகும் ராணி
குறுக்குச் சோழனை மற்றும் பஞ்சு 
சோழனைன் ராணி
நீதியால் கருப்பிதம் விரும்பு
விருப்பு மக்கில் காணும்
பிடிகும் ராணி
பஞ்சு
பஞ்சு மக்கில் காணும்
பக்கமாகிய பஞ்சு மக்கில் காணும்"

-சது மார்த.

However, it is always worth trying to assess Nadi in children when it was quite apprehendable. In cases of Virana silethumam, vatha pitham was apprehended commonly followed by Pithakabam and kaba pitham. It correlates with *Paripurana Nadi* as follows,

"மீதியால் புள்ளி புள்ளிகள் மக்கில்
"
(Tri-humoral Derangements):

It is the derangement of three vital Humors (ie) Vatham, Pitham and Kabam.

1. **Vatham**

Vatham is a kinetic energy influencing all movements, located in the abanan, idakalai, faeces, spermatic cord, iliac bone, skin, nerves, joints, hair follicles, muscles, bone, ear and thigh.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Name</th>
<th>Locations</th>
<th>Physiologic Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Piranan</td>
<td>Heart and Lower and Upper Respiratory Tracts</td>
<td>Controls knowledge, mind and five objects of sense, useful for breathing</td>
</tr>
<tr>
<td>2</td>
<td>Abanan</td>
<td>Lower abdomen and extremities</td>
<td>Responsible for urination, expels faeces and foetus, discharge of sperm and menstruation.</td>
</tr>
<tr>
<td>3</td>
<td>Viyanan</td>
<td>Mainly at heart</td>
<td>Responsible for movement of all parts of the body and used to feel the sensation</td>
</tr>
<tr>
<td>4</td>
<td>Uthanann</td>
<td>Chest</td>
<td>Responsible for vomiting, cough, hiccough, sneezing</td>
</tr>
<tr>
<td></td>
<td>Vayu</td>
<td>Organ</td>
<td>Function</td>
</tr>
<tr>
<td>---</td>
<td>------------</td>
<td>----------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>5</td>
<td>Samanan</td>
<td>Stomach</td>
<td>Aids for proper digestion. It controls the activity of other vayus</td>
</tr>
<tr>
<td>6</td>
<td>Naagan</td>
<td>Eyes</td>
<td>Responsible for opening and closing of the eyes</td>
</tr>
<tr>
<td>7</td>
<td>Koorman</td>
<td>Heart and Eyes</td>
<td>Responsible for vision and yawning and controls lacrimation</td>
</tr>
<tr>
<td>8</td>
<td>Kirukaran</td>
<td>Throat</td>
<td>Responsible for salivation nasal secretion and appetite</td>
</tr>
<tr>
<td>9</td>
<td>Thevathathan</td>
<td>Eruvai &amp; Karuvai</td>
<td>For laziness, sleeping and anger</td>
</tr>
<tr>
<td>10</td>
<td>Thananjeyan</td>
<td>Nose</td>
<td>Responsible for bloating of the body after death. It escapes on the third day after death through the cranium when it bursts.</td>
</tr>
</tbody>
</table>

In Virana silethumam, the following are affected,

1. Uthanan: cough, sore throat, difficulty to swallow
2. Samanan: poor control of other vayus
3. Kirukaran: poor appetite, nasal secretion,
4. Devathathan: malaise, sleepiness
5. Abanan: constipation, passing of hard stools
2. பிதம் (Pitham):

Pitham is the Fuelling energy located in urinary bladder, heart, head, umbilicus, abdomen, blood, sweat, skin and eyes. Pitham is classified into 5 types.

They are,

1. Anal Pitham - Responsible for the digestion of food.
2. Ranjaga pitham - Responsible for the colour of blood.
3. Sathagam - Located in heart and is responsible for normal activities of the body.
4. Alosagam - Responsible for normal vision
5. Prasagam - Responsible for the complexion of skin.

In virana silethumam, the following can be affected
1. Analam – poor appetite
2. Renjagam – pallor of body, conjuctiva, nail bed

3. கபம் (Kabam):

It is the restorative energy that stabilizes, maintains and lubricates all organs. Kabam is found in samanan, semen, brain, head, tongue, nose, bones, bone marrow, fat, nerves, chest, blood, large intestine, eye, stomach and pancreas.

Kabam is classified in to 5 types, they are,

1. Avalambagam : Heart is the center for Avalambagam, It controls all other forms of kabam.
2. Kilethagam : Stomach is the center for kilethagam. It gives moisture and softness to the ingested food and helps for digestion.
3. Pothagam : Tongue is the center for pothagam and it is responsible for the sense of taste.
4. Tharpagam: Head is the center for tharpagam. It gives cooling effect to eyes.

5. Santhigam: It lies in the joints and is responsible for the locomotive action of movable bony joints.

Sometimes, pothagam may be affected producing distaste in silethuma diseases.

7 Physical Constituents:

Udal Kattugal are 7 in number as follows,

1. Saaram: It is the final product of the digestive process, which gives strength to the body and mind.

2. Senneer: Saaram after absorption is converted into senneer. It is responsible for knowledge, strength, boldness, and healthy complexion.

3. Oon: Gives structure and shape to the body and is responsible for the movement of the body.

4. Kozhuppu: Lubricates the organs and proceed on its own works.

5. Enbu: Protects the vital organs and used for movements and nominates the body structure.

6. Moolai: Present inside the bones and it gives strength and maintain the normal condition of the bone.

7. Sukkilam/Suronitham: Responsible for the reproductive functions of the species.

In Virana silethumam, Saaram is affected in all patients and Senneer is affected in some of the patients.
**Seasonal Variations:**

The whole year is constituted by six seasons. They are,

<table>
<thead>
<tr>
<th>S.No</th>
<th>Kaalam</th>
<th>Kuttram</th>
<th>State of Kuttram</th>
<th>Suvai</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pitham ↑</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pitham ↑↑</td>
<td>Vetrunilai Valarchi.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Munpani Kaalam (Markazhi – Thai) (Dec16 – Feb15)</td>
<td>Pitham (–)</td>
<td>Thannilai Adaithal</td>
<td>Enippu, Pulippu, Uppu</td>
</tr>
<tr>
<td>4</td>
<td>Pinpani Kaalam (Masi – Panguni) (Feb16 – Apr15)</td>
<td>Kabam ↑</td>
<td>Thannilai Valarchi.</td>
<td>Enippu, Pulippu, Thuvappu</td>
</tr>
</tbody>
</table>
The incidence of viranasilethumam is predominant in Koothir kaalam and Munpani Kaalam. But also occurs in other kaalam, because of life style modification.

According to silethuma roga ilambagam, kabam
- Starts to increase in masi, panguni
- Overflows from actual sites to spread in aadi, aavani, purattasi.
- Reaches its maximum during vaigasi.

(FIVE TYPES OF LANDS):
It is divided into five types.
1. Kurinji : Mountain regions and surroundings.
5. Palai : Desert land only.
In Kurinji nilam kaba disease are common. In Palai nilam all disease can be caused by deranged vatha, pitha and kaba thodam. Pitha diseases are widely seen in Mullai nilam. Virana silethumam can occur in any nilam since the dietary patterns and habits of the patients can vitiate the Kaba thathu.

**Body Immunity:**

Smartness, strength and vitality constitute Udal Vanmai. It is classified into 3 types as

1. **Iyarkai Vanmai:**
   - Natural immunity of the body itself by birth.

2. **Seyarkai Vanmai:**
   - Improving the health by intake of nutritious food materials, activities and medicines.

3. **Kaala Vanmai:**
   - Development of immunity according to age and the environment.

The Vanmai of the children plays an important role in causing the disease and development of recurrent nature. Child’s vanmai is affected by mother’s deeds during pregnancy, in addition to intake of unwanted foods, unhealthy habits by the child and climatic changes.

**Treatment:**

"&lt;em&gt;“&lt;/em&gt;&lt;strong&gt;ஒற்றையே விசயம் வைக்க மிக்கும் நூற்றாண்டு&lt;/strong&gt;

&lt;em&gt;மற்றும் கருவகாலி விளக்கங்கள் மற்றும் நேரான விளக்கங்கள்

&lt;em&gt;நிலான உயிரியுறுத்து நீராய்வுக்கான குறுக்கு நூற்றாண்டு.”&lt;/em&gt;"

-&lt;em&gt;குருவாலாகன் குருவாலாக&lt;/em&gt;
The author of the poem recommends that all types of silerpana rogams can be cured if the each type is treated with appropriate medicine after knowing the exact nature of illness.

Siddha treatment is not only for complete healing but also prevention and rejuvenation. The three facets of a vital Siddha therapy involves the following:

1. **Preparation - Prevention:**

   In any health system, emphasis of “Prevention is better than Cure” is first step in treating a disease. Emulation of healthy diet pattern with sattvic foods, daily habit forms, prophylactic measures to preserve child’s growth and immunity is essential. This forms the basis of parental counselling to strengthen the seyarkai vanmai of the child to prevent deterioration of host immune response to microbial invasion as in case of Virana silethumam. Developing awareness among mothers regarding preventive aspects facilitates reduction in incidence of silethumam diseases among pediatric population.

**Prevention methods:**

- To avoid chill and cold weather.
- To dress according to weather conditions.
- To avoid eating outside frequently.
- To avoid cold food stuffs, ice creams, etc.
- To avoid contaminated food and water.
- To avoid unhealthy habits like nail biting, thumb sucking, pica etc.
- To find out which agent makes allergy and avoid them.
2. சேதகம் – Treatment:

Line of Treatment:
The line of treatment as suggested by PillaiPini Maruthuvam states:
To neutralize the vitiated Kapham and remove phlegmatic secretions,
- Expectorant
- Stimulants
- Anti-spasmodics can be given.
To relieve fever, sore-throat and headache,
- Febrifuge
- sedatives
- Diaphoretics
- Demulcents can be used.
Siddhars ideology proves meticulous combinations of dry and heat characters with silethumam can neutralise the deranged kabam. This helps in curing grave diseases.

Anupanam in Siddha system:

“அனுபானம் துணைமருந்து பெறுத்து பயன்படுத்து
முக்கிலசு இனங்கு கலக்கு திரு - பிரமுறக்கு
சிற்றமை பார்வையளவில் விளக்கும் விளக்கும் வழக்கிலே
அதிசம் வழங்கிச் சீர்காட்டு”
-தொற்று தம்பு.

Anupanam (Thunai marunthu) is considered vital in siddha without which there cannot be success in treatment. According to dictionary of TVS, vehicle employed goes to modify the quality or active principle of the medicine itself, thus rendering the potency and curative power consistent with the nature of the disease for which it is administered. This point goes synchronous with milk in treating silethuma ailments
Pathiyam:

Pathiyam comprises a list of dietary, habitary pattern that has to be followed to equalize the deranged kuttrams and the restrictions help in enhancement of drug action in addition to favouring quick recovery from the illness.

For patients of kabam disorders, the following are suggested.

“குடறல் பெரும்பாலும் வரல் பிரிவாக்கம் புரட்சிக்கான களங்கள்
அத்தோ காப்பாக புரட்சிகக்காலம் காட்சிகள் பிரிவுகள்-பிரிவினங்களை
பொறுப்புத் தரவிட கற்கள் கல்லக் கருத்துகள் பொருளாதி புரட்சிக்கும்
அதில் புறாக்கு காப்பாகக் கருத்து கருத்துப் பாதுகாப்புக்கான காட்சிகளை.
விநாயக வல்லாக்கள் பூச்சிக் கட்டுமானது
முடிவு வாய்ந்த கூட்ட பெரும்பாலானவர்களை-பிரிவினங்களை
பிற்காலிச் காட்சிகள் வேளாக் வெயிலக் கல்லக் கருத்து விளம்பாக்காக காட்சிகளை.”

-புரட்சிக் காய் பிரிவாக்கள்.

Diet Restriction:

- Avoidance of cold drinks, cold food items, cold water, sour fruits like sapota, banana, oranges, lemon, sweet lime, grapes, watery veggies were advised.
- Intake of hot milk with turmeric, pepper and palm candy at nights advised.
- Intake of one among ginger, pepper, thoothuvelai, karisalanganni and manathakkali leaves as rasam, curry, thuvayal or adai was recommended.
- In non-vegetarians, intake of certain varieties of fish, field crab and mutton liver soup were advised.
- In addition, intake of timely, hot easy digestible foods was stressed.
3. **Restoration:**

- Reassurance of disease recovery was given to all patients.
- The children and their parents were advised to follow the essential elements of Siddha dietary, habit pattern and preventive methods to ensure that the illness does not recur.
MODERN ASPECTS

TONSILS AND ADENOIDs

ANATOMY:

The tonsils are pairs of soft tissue masses located at the rear of the throat (pharynx). Each tonsil is composed of tissue similar to lymph nodes, covered by pink mucosa (like on the adjacent mouth lining). Running through the mucosa of each tonsil are pits, called crypts.

WALDEYER RING:

There are superficial masses of lymphoid tissue in the pharyngeal mucosa, which form a ring that acts as a *filter*, protecting the body against infecting organisms that might enter it from the nose or mouth. This ring of lymphoid tissue surrounding the oral and nasal openings into the pharynx is called "Waldeyer's Ring". It includes

1) Palatine tonsil
2) Pharyngeal tonsil/ adenoid
3) Lymphoid tissue surrounding Eustachian tube orifice into the lateral walls of the naso pharynx.
4) Lingual tonsil at the base of the tongue
5) Scattered lymphoid tissue throughout the remainder of the pharynx but especially behind the posterior pharyngeal pillars and along the posterior pharyngeal wall.

PALATINE TONSIL:

Lymphoid tissue located between the palato-glossal fold (anterior tonsillar pillar) and the palato pharyngeal fold (posterior tonsillar pillar). This is separated from the surrounding pharyngeal musculature by a thick fibrous capsule.
**ADENOID:**

Single aggregation of lymphoid tissue occupies the space between the nasal septum and the posterior pharyngeal wall. A thin fibrous capsule separates it from the underlying structures. Adenoid does not contain complex crypts that are found in the palatine tonsils but rather simpler crypts.

**LINGUAL TONSIL:**

Lymphoid tissues at the base of the tongue contain simpler tonsillar crypts.

**PHYSIOLOGY:**

Approx 65% of the lymphocytes that make up for the Waldeyer Ring are B-Lymphocytes, the remainder being either T-Lymphocytes or plasma cells.

The immunologic role of the tonsils and adenoid is to induce secretory immunity and to regulate the production of secretory immunoglobulins. Situated at the opening of the pharynx to the external environment, the tonsils and adenoid are in a position to provide primary defense against foreign matter. The Deep crevices within tonsillar tissue form tonsillar crypts that are lined with squamous epithelium but have a concentration of lymphocytes at their bases. Lymphoid tissue of Waldeyer Ring is most immunologically active between 4 and 10 years of age, with a decrease after puberty.

Recent studies have indicated the existence of an active cellular defence in the secretion on the tonsillar surface. This defence seems to consist partly of physiologically active neutrophils and is present in health and during disease.

**NORMAL FLORA OF MOUTH AND UPPER RESPIRATORY TRACT:**

The mouth contains a plethora of organisms-pigmented and non-pigmented micrococci, some of which are aerobic, Gram positive aerobic spore bearing bacilli, coliforms, proteus and lactobacilli. The gum pockets between the teeth and the crypts of the tonsils have a wide spectrum of anaerobic flora – anaerobic micrococci, microaerophillic and anaerobic Streptococci, Vibrios, Fusiform bacilli, Corynebacterium species, Actinomyces, Leptothrix, Mycoplasma, Neisseria hemophilus, Branhamalla and
Bacterioides are all found in varying extents. Among fungi, Candida and Geotrichum have been reported.

The mouth of the infant is not sterile at birth. It generally contains the same types of organisms in about the same relative numbers as those present in the mother’s vagina that is a mixture of Micrococi, Streptococi, Coliform bacilli and Doderlein’s bacilli. These organisms diminish in number during the first 2-5 days after birth and are replaced by the types of bacteria present in the mouth of the mother and nurse.

Within 12 hours after birth alpha hemolytic streptococci are found in the upper respiratory tract and become the dominant organisms of the oropharynx and remain so for life. In the pharynx and trachea, flora similar to that of mouth establishes themselves. Few bacteria are found in normal bronchi. Smaller bronchi and alveoli are normally sterile.

The commensals from the normal flora of the mouth, nasopharynx may get into the blood and tissues. They are usually quickly eliminated by the normal defence mechanism of the body; occasional diphtheroids or non-hemolytic streptococci from normal and abnormal lymph nodes may be those which escaped elimination. Unless the organisms of doubtful pathogenicity are isolated more than once in serial blood cultures, they have little significance.

PATHOLOGY:

**ACUTE INFECTION:**

Most episodes of acute pharyngotonsillitis are caused by viruses such as Adenovirus, coronavirus, enterovirus, rhinovirus, respiratory sychnitial virus (RSV), Ebstein Barr Virus, Herpes Simplex Virus and Metapneumo virus. Next to viral infections, GABHS is being the most common cause of bacterial infection in the pharynx. Additional bacterial organisms can include other beta-hemolytic streptococci, Group C, Staphylococcal aureus, gram negative organisms, Mycoplasma pneumoniae, Neisseria gonorrhoea and Corynebacterium diphtheriae.
Oral candidiasis can occur in immunocompromised children who have been treated chronically with antibiotics or inhaled steroids.

**CHRONIC INFECTION:**

Occurs by multiple microbes, which include high incidence of beta-lactamase producing organisms such as;

- Aerobic: Streptococci, H.influenzae,
- Anaerobic: Peptostreptococcus, Provotella, Fuobacterium predominate etc.

**TONSILLAR CRYPTS:**

The accumulated desquamated epithelial cells, lymphocyte, bacteria and other debris cause cryptic tonsillitis. These cryptic plugs can calcify into tonsillar concretions or tonsilloliths.

**AIRWAY OBSTRUCTION:**

Both the tonsil and adenoid hypertrophy are a major cause of upper respiratory tract obstruction in children.

**TONSILLAR NEOPLASM:**

Rapid enlargement of one tonsil is highly suggestive of a tonsillar malignancy, typically lymphoma in children.
NORMAL THROAT

Tonsils hidden behind anterior faucial pillar

Anterior Faucial pillar (mucosa of soft palate covering tonsil)

Uvula
Soft Palate
Tongue
Teeth

Normal Healthy Throat and Airway.  Enlarged Crowded Tonsils.
Acute Pharyngo-tonsillitis

Tonsillitis with exudates
ACUTE PHARYNGOTONSILLITIS

DEFINITION:

Acute inflammation generally restricted to the tonsils, posterior pharynx, uvula, posterior palate and the lymph nodes of the Waldeyer’s lymphatic ring that drain the anterior cervical region. Acute pharyngotonsillitis is an infection restricted to the crypt and surface secretion. When referring to tonsillitis, the correct term is pharyngo-tonsillitis (PT) as the pharynx has lateral cords with the same type of tissue as in Waldeyer’s lymphatic ring.

In previous studies on acute pharyngotonsillitis, it is found that the secretion in crypts and at the surface was infected in acute pharyngotonsillitis while no bacteria were detected in the parenchyma. Based on these results, researchers have proposed a new hypothesis stating that the infection is restricted to the crypt and surface secretions in acute pharyngotonsillitis.

EPIDEMIOLOGY:

In a survey involving 429 pediatricians in the United States, Upper respiratory tract infections and ear infections were the most common causes for a visit. Pharyngo-tonsillitis was the third most common problem, responsible for 17% of the visits, according to the age of the child.

PREVALENCE AND DISTRIBUTION:

GAS most often affects children and young adults (5-15 years of age). Infection is most common during the winter and early spring. GAS is the cause of approximately 15-30% of acute pharyngo-tonsillitis in children and 5-10% in adults.
ETIOLOGY:

**VIRAL:**
Adenovirus, Rhinovirus, Coxsackie viruses A & B, influenza virus, Para influenza virus, Echo virus and Respiratory Syncytial virus and Epstein Barr virus.

**BACTERIAL:**
Usually caused by Group A Beta-Hemolytic streptococci. Less common pathogens include S.aureus, H.influenzae, M.catarrhalis, Diphtheriae, Gonococci, chlamydiae.
Mycoplasma pneumoniae and Candida albicans have also been incriminated.
Irritant fumes and smoke also cause irritation of the throat.

MICROBIOLOGY:
In a study, about 54% of the patients, an initial throat swab did not grow any pathogenic organism. Positive swabs were mostly of GABHS or Staphylococcus aureus. Group A -haemolytic streptococcus (GABHS) is one of the major causes of tonsillitis. However, other aerobic and anaerobic organisms can be isolated from the surface and core of normal and inflamed tonsils. The exact role of these organisms is uncertain, and some are believed to be part of the normal oropharyngeal flora, as we saw earlier. Anaerobic bacteria predominate in the normal oral flora, outnumbering aerobic bacteria in a ratio of 10:1.

- GABHS is the best known cause of pharyngotonsillits,
- Occasionally, groups B, C and G beta-hemolytic streptococci are responsible, *Streptococcus pneumoniae* infections may be self-limited or it may spread to other sites,
- *Corynebacterium diphtheriae* produces a lethal exotoxin that is absorbed from the site of infection and carried to other organs, such as the throat, palate, and larynx.
- *Arcanobacterium hemolyticum* infection affects the 15-18-year age group and accounts for 2.5-10% of all cases of pharyngotonsillitis.
- *Neisseria gonorrhoeae* infection is more common in homosexual males and may be associated with pharyngitis in adolescents. It can result in bacteremia and may persist after treatment.
- *Neisseria meningitidis* can cause symptomatic or asymptomatic pharyngotonsillitis which can be a prodrome for septicemia or meningitis.
- *Staphylococcus aureus* is often isolated from chronically inflamed tonsils and peritonsillar abscesses. The bacterium produces betalactamase which can interfere with the eradication of GABHS.
- Nontypable *H. Influenzae* and *H. parainfluenzae* may be recovered from inflamed tonsils. These agents can cause invasive disease in infants and the elderly, as well as acute epiglottitis, otitis media, and sinusitis. High tissue concentrations of *H. Influenzae*, *Staphylococcus aureus* and GABHS correlate with clinical parameters of recurrent infection and hyperplasia of the tonsils.
- In rare cases, pharyngotonsillitis is caused by *Francisella tularensis*, *Treponema pallidum*, *Mycobacterium* spp, or *Toxoplasma gondii*.
- The anaerobic species that have been implicated in pharyngotonsillitis are *Actinomyces*, *Fusobacterium*, and gram negative bacilli (e.g. pigmented *Prevotella* and *Porphyromonas* spp., and *Bacteroides* spp.). The role of anaerobes is supported by their predominance in tonsillar or retropharyngeal abscesses and Vincent's angina (Fusobacterium spp. and spirochetes).
- Elevated serum levels of antibodies to *Prevotella intermedia* and *Fusobacterium nucleatum* have been found in patients with recurrent non-GABHS tonsillitis and peritonsillar cellulitus and abscess.
- *Mycoplasma pneumoniae* and *Mycoplasma hominis* can also cause pharyngotonsillitis, usually as a manifestation of a generalized infection. The prevalence of *Mycoplasma* infection increases with age.
- *Chlamydiae pneumoniae* infection often accompanies pneumonia or bronchitis.
PRECIPITATING FACTORS:

In children, history of attacks is precipitated by intake of cold drinks (aerated drinks as well as juice), ice-creams, fried items and passive smoking. These factors could possibly be acting by

- Altering the bacterial micro flora and/or
- Lowering host immunity by altering local factors in the throat.

TRANSMISSION:

Major source of the streptococcus pyogenes is the human upper respiratory tract ie. Throat, nasopharynx or nose of the patients and carriers. Nasopharynx and oropharynx are the main sites of colonization. Carrier rates of up to 20% have been observed.

Aerosol secretions of the upper respiratory tract are the primary transmitting source of the causative agents. Transmission is either by direct contact or through contaminated fingers, dust or fomites.

Risk of contagion depends on the amount that was inoculated and on the virulence of the strain. Thus, individuals are more prone to become infected in the early stages of disease. Crowding is an important factor in the transmission of infection. Outbreaks of infection may occur in closed communities such as boarding schools or day care centers.

The incubation period is from 1 to 4 days and most physicians allow children to go back to school 48 to 72 hours after the antimicrobial treatment is started. The rate of transmission of GAS in untreated patients is approximately 35% in close contacts, such as family members or schools.
GENERALISED CLINICAL FEATURES:

Irrespective of the type of Pharyngotonsillitis, the following are the classical features

**Symptoms**
- Odynophagia,
- sorethroat,
- malaise, fever and chills,
- dysphagia,
- referred otalgia,
- headache,
- muscular aches and
- enlarged lymph nodes.

**Signs**
- Dry tongue,
- Erythematous enlarged tonsils,
- Tonsillar/pharyngeal exudates,
- Palatine petechiae,
- Enlargement & tenderness of jugulo-digastric lymphnodes.

**VIRAL PHARYNGOTONSILLITIS:**

The predominance of viral infections is very high in children younger than 3 years of age, an age group where pharyngo-tonsilitis caused by GABHS is rare. The onset is gradual and there is less toxaemia. An irritation of the pharynx / tonsils is frequently found with viral infections.

Children with viral infections often have extra-pharyngeal signs and symptoms, as nasal secretions, conjunctivitis, cough, hoarseness, diarrhea, ulcerations or other clinical manifestations highly suggestive of viral infections.
It presents with grayish or yellowish white discrete areas of exudate on tonsils with pharyngeal erythema and tender cervical lymphadenopathy.

The classical symptoms of viral infections namely, cough, rhinitis, conjunctivitis, and diarrhea, are usually absent in bacterial pharyngotonsillitis. (According to the clinical index developed by McIsaac and colleagues)

**BACTERIAL PHARYNGOTONSILLITIS:**

GABHS has been the most common cause of acute pharyngotonsillitis, its importance not only lies in the frequency but due to its serious sequelae ie, acute rheumatic fever and post streptococcal glomerulonephritis.

The onset is sudden, acute, charachterised by odynophagia, high fever, headache and abdominal pain.

Signs and symptoms of pharyngotonsillitis caused by GABHS can vary from mild pain in the throat and malaise (30% to 50% of cases) to high fever, nausea, vomiting and dehydration (10% of cases).

The mucosa in the pharynx and tonsils is typically hyperemic, with occasional edema, exudate being present in 50% - 90% of the cases.

Petechiae or doughnut lesions on the soft palate or posterior pharynx. Uvula is red, stippled and swollen.

Cervical adenopathy is very common (30% - 60% of cases). When present in the classical form, the scarletiniform exanthema is very indicative of a bacterial infection, but is not frequent. GABHS pharyngotonsillitis tends to present with exudative pharyngitis.

Younger children may not complain of sorethroat but often refuse to feed normally.

**COURSE OF ILLNESS:**

Viral pharyngotonsillitis is usually associated with nasal secretions and is generally self-limited (4-10 days), whereas bacterial illness, if left untreated, lasts longer.
DIAGNOSIS:

Most infections around waldeyer’s ring are polymicrobial in nature and often it is difficult in interpreting data of samples and differentiating between the organisms that are colonized and those that are invaders. Several studies have documented that most physicians empirically start antimicrobial therapy for suspected acute pharyngitis and may not collect a swab for throat culture\textsuperscript{10}.

1. Complete Blood Count (CBC): Neutrophil count in the peripheral blood is elevated in streptococcal infections.
2. An increase in antistreptolysin O (ASO) streptococcal antibody titer after 3-6 weeks can provide retrospective evidence of GABHS infection. The usual test done is anti streptolysin O titration. ASO Titres $> 200$ are indicative of prior streptococcal infection.
3. High CRP value is seen in streptococcal infections. In patients with streptococci group C or G an elevated CRP-value was significantly associated.
4. Culture from the tonsils, tonsil crypts or pharynx : was earlier considered as golden standard for the definite etiologic diagnosis of a Pharyngo tonsillitis (due to 95% specificity in GABHS identification) but now judged to be an imperfect gold standard for diagnosing streptococcal pharyngitis because of the following:
   a. False positive cultures can occur if the organisms are misidentified as GABHS.
   b. Children who are streptococcal carriers can also have positive cultures.
   c. False negative cultures are attributed to a variety of causes including inadequate throat swab specimens and patients surreptious use of antibiotics.
5. Rapid Streptococcal antigen detecting test: Gives result within 10 minutes. The specificity is high. If rapid test is positive, indicates appropriate treatment.
6. If rapid strep test is negative, confirmation with throat culture is considered mandatory on account of clinical suspicion of GABHS.
7. Viral cultures often unavailable. It is too expensive and too slow to be clinically useful.
8. Viral Polymerase Chain Reaction (PCR): more rapid and may be useful but not always necessary.
9. Monospot or Paul-Bunnel Test or Slide Agglutination test: helps confirm EBV infectious mononucleosis.
10. A lateral soft tissue X ray film of the Head and Neck region will show up the hypertrophic tonsils and adenoids together with narrowing of naso and oropharynx.

Short duration of symptoms, considerable pain on swallowing, an age of 3 to 14 years, an elevated CRP value and four Centor criteria (fever, anterior cervical lymphadenopathy, tonsillar rubor and exudates, and lack of cough) are of significant value in diagnosing streptococcal pharyngotonsillitis.

For tonsillar hypertrophy, the following scale is usually used in clinical practice.

**Size & Percentage of Obstruction:**

1. **GRADE 0**: tonsil is in fossa
2. **GRADE 1**: less than 25% obstruction
3. **GRADE 2**: less than 50% obstruction
4. **GRADE 3**: less than 75% obstruction
5. **GRADE 4**: more than 75% obstruction.

In adults, the Centor criteria are most often used. The 4 criteria are:

1. Tonsillar exudates;
2. Tender anterior cervical adenopathy;
3. Fever by history;
Persons with three or four of these criteria may be treated empirically for GAS. Those with zero or one criterion do not need to be tested or treated. If two or three criteria are present, testing should be performed and patients treated only if the test is positive.

The McIsaac modification of the Centor criteria is being used nowadays in children. Points for a patient are added based on the following scoring:

1. history of fever or T>101°F (38°C) +1
2. absence of cough +1
3. tender anterior cervical adenopathy +1
4. tonsillar swelling or exudates +1
5. age <15 years +1
6. age ≥ 45 years -1

Children with 0 points are unlikely to have GAS infection and do not need to be tested. Those with 1-3 points should be tested and treatment based on the test result. Those with 4-5 points have a high likelihood of having GAS infection and may be treated empirically or tested and treated if the test is positive.

**ASSESSMENT:**

The improvement in case of pharyngo-tonsillitis can also be assessed by the improvement in the symptoms such as difficulty in feeding in small children, mouth breathing, noisy respiration, loud snoring, frequent awakening or hypersomnolence, secondary enuresis, night terrors or changes in behaviour pattern (Pavor Nocturnus).

Regular monitoring of the improvement in the symptomatology proves to provide clue for clinical prognosis and assessment of management.
DIFFERENTIAL DIAGNOSIS:

1. Narrowing and spasm of trachea and bronchi may also cause sensation of sore throat with a constant desire to clear the throat.

2. Primary HSV infections in young children often present as high fever and gingivostomatitis but pharyngitis may be present.

3. Herpangina: it is an acute febrile illness due to the group ‘A’ Coxsackie virus. Patients have dysphagia, sore throat and papulovesicular lesions surrounded by erythema over the tongue, pharynx, anterior tonsillar pillars and soft palate. Pharynx appears congested with the presence of small yellowish white nodules.

4. Diphtheria: Corynebacterium diphtheriae infection causes a bull neck and an early exudative pharyngotonsillitis characterized by the development of a grayish-green thick membrane that is difficult to dislodge, and when torn off, often leaves a bleeding surface. Associated moderate fever and toxaemia are present.

5. Agranulocytosis: Blood count shows neutropenia.

6. Pharyngoconjunctival fever: patients have fever, conjunctivitis, pharyngitis and cervical lymphadenitis due to infection with adenovirus type III.

8. Gonococcal pharyngeal infections are usually asymptomatic though some exhibit pharyngeal ulcers or exudates. It can cause acute pharyngitis with fever and cervical lymphadenitis.

9. Mycoplasma pneumoniae infection occurs only in early adolescence.

**COMPLICATIONS:**

Many of the pharyngotonsillitis complications include the obstructive, infectious, toxin-mediated or immunomediated.

**OBSTRUCTIVE:**

Patients with tonsillar hyperplasia can have breathing difficulties, in general when the acute tonsillar inflammation leads to edema. In certain infections, as caused by the Epstein Barr virus, the degree of edema can be so severe that tonsils that are generally non-obstructive can interfere with breathing. This is typically manifested in sleep-disordered breathing including Obstructive sleep apnea, Hyperpnoea and upper airway resistance syndrome.

**INFECTIOUS:**

This includes both suppurative and non-suppurative. Streptococcus pyogenes infections lead to two important non-suppurative sequelae.

- **Acute glomerulo-nephritis (AGN):** the acute nephritic syndrome can develop 1 to 2 weeks after an acute streptococcal infection and complicates approximately 5% of cases of GABHS pharyngitis in children. The early administration of antibiotics does not prevent this sequela. The most frequent form of AGN is the IgA-mediated nephropathy, associated with chronic tonsillitis.

- **Acute Rheumatic fever (ARF):** it is the most serious infectious complication of the acute streptococcal Pharyngotonsillitis. ARF happens in < 3% of untreated cases of GAS during an epidemic and in < 0.5% of sporadic cases. It ensues 1 to 3 weeks after the acute infection so that the organism may not be detectable when
sequelae set in. this clinical entity presents with triad of arthritis, carditis and chorea. It can also lead to a heart valve disease ie, mitral stenosis.

From the throat, streptococci may invade to the surrounding tissues, leading to **suppurative** complications such as

- Otitis media
- Sinusitis.
- Peritonsillar abscess is the most common infectious complication resulting from an extensive acute exudative tonsillitis.
- Retropharyngeal or parapharyngeal abscesses.
- Mastoiditis
- Quincy
- Ludwig’s angina
- Suppurative cervical adenitis.
- Supraglotitis
- Cellulitis
- Fasciitis
- Peritonitis
- Arthritis
- Osteomyelitis
- Thyroditis
- Meningitis
- Bacteremia
- The infection may spread down the tracheobronchial tree causing tracheobronchitis and pneumonia.

Therapy with antibiotics can prevent the above suppurative complications and rheumatic fever among non-suppurative complications. However, a final conclusion has not been reached yet about post-streptococcal acute glomerulonephritis being prevented by antibiotic therapy.
TOXIN-MEDIATED:

- Scarlet fever is a classical, toxin-mediated form of infection by GABHS
- Another toxin mediated disease associated with GABHS is the necrotizing fasciitis or Toxic shock syndrome.
- Recently a new syndrome called PANDAS (Pediatric Autoimmune Neuropsychiatric Disorder Associated with Group A Streptococci) has been described. The syndrome involves obsessive-compulsive disorder or tic disorder with other neurologic abnormalities of abrupt onset in association with GABHS infections. A clear cut relationship between the syndrome and GABHS infection is yet to be published.

TONSILLECTOMY:

The most followed curative treatment nowadays is surgical removal of tonsils. Adenoidectomy & Tonsillectomy are currently one among the top 10 pediatric surgeries.

In the first century AD, Celsus described tonsillectomy performed with sharp tools and followed by rinses with vinegar and other medicinals. Since that time, physicians have been documenting surgical management of tonsillitis.

INDICATIONS FOR TONSILLECTOMY:

The current clinical indications for tonsillectomy are:

(As recommended by the AAO-HNS in 2000)

- An important indication is recurrent or chronic pharyngo-tonsillitis.
- 3 or more infections per year despite adequate medical therapy.
- Hypertrophy causing dental malocclusion or adversely affecting oro-facial growth documented by orthodontist
- Hypertrophy causing upper airway obstruction, severe dysphagia, sleep disorders (obstructive sleep apnea)
- Unilateral tonsil hypertrophy presumed to be neoplastic.
- Cardiopulmonary complications
- Peritonsillar abscess unresponsive to medical management and drainage documented by surgeon (except when surgery is performed during acute stage)
- Persistent foul taste or breath due to chronic tonsillitis not responsive to medical therapy;
- Previous peritonsillar abscess may be a relative indication.
- Significant missed time from school or work should prompt for tonsillectomy.

**DEMERITS OF TONSILLECTOMY:**

- Tonsillectomy and adenoidectomy results in a major loss of pharyngeal lymphoid tissue.
- Dehydration from odynophagia is common in the first post operative week.

- Immunization against poliomyelitis in post-tonsillectomy patients has a higher incidence of bulbar poliomyelitis.
- Swelling of the tongue and soft palate may lead to acute airway obstruction in the first few hours after surgery. Children with underlying hypotonia or craniofacial anomalies are at greater risk of suffering this complication
• Bleeding may occur in the immediate post-operative period or be delayed after separation of eschar. Postoperative hemorrhage is considered the most significant risk.

• Rare complications include velopharyngeal insufficiency, nasopharyngeal or oropharyngeal stenosis

• Psychological problems.

• Tonsillectomy has not shown to offer clinical benefit over conservative treatment in children with mild symptoms. Furthermore, tonsillectomy does not prevent recurrence of pharyngeal infections.

• No significant difference exists between the type and number of pathogens in patients undergoing adenotonsillectomy for recurrent infection or obstruction^24&25.

CARRIERS:

Patients exposed to GABHS can continue to asymptptomatically “carry” the organism, even after an appropriate antimicrobial therapy. Carriers are recognized as individuals that have a positive culture for this organism, although there is a very low risk that they will transmit GABHS or even develop sequelae. The rate of carriers reported in the literature varies from 3 to 40% depending upon the population being assessed.

TREATMENT:

Most untreated episodes of Streptococcal pharyngo-tonsillitis resolve uneventfully in a few days, but early antibiotic therapy hastens clinical recovery by 12 to 24 hours. The treatment should be aimed at relieving symptoms of the acute disease (antipyretics, analgesics), eliminate transmissibility; prevent both suppurative and non-suppurative sequelae. When selecting an antimicrobial for treatment of group A
streptococcal pharyngo-tonsillitis, important issues to consider include efficacy, safety, antimicrobial spectrum (narrow vs. broad), dosing schedule, associated compliance with therapy (i.e., adherence) and cost. These factors influence the cost-effectiveness of antimicrobial therapy.

RECURRENT EPISODES OF PHARYNGOTONSILLITIS:

The criteria is

- 7 or more throat infections treated with antibiotics in the preceding year
- 5 or more throat infections treated in each of the preceding two years
- 3 or more throat infections treated with antibiotics in each of the preceding three years.

In order to control the recurrency, following strategies are to be followed:

- Smoky and dusty atmosphere should be avoided.
- Dampness in the environment and overcrowding are to be better avoided.
- Child’s general health should be improved by good nutritious diet.
- A detailed history should be obtained and physical examination conducted for proper evaluation.
- Paranasal sinuses and ears should be examined for the foci of infection and if present, should be adequately treated.
**DRUG REVIEW**

**(PROPERTIES OF TRIAL DRUG INGREDIENTS)**

\[\text{Coriandrum sativum, Linn}\]

**Botanical Name:** Coriandrum sativum, Linn

**Classical /Vernacular Names:** கரியான்மை, கரியான்மை

**Natural Order:** Apiaceae

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**Botanical Description:**

Fruits yellowish brown, globose, 4-5 mm in diameter, ribbed, separating into two halves. Seeds compressed.

**Parts Used:** Whole plant, fruit

**Pharmacognosy:**
Fruits is subglobose, glabrous, schizocarp, about 5 mm in diameter, splitting into two hemispherical mericarps. Each mericarp has 5 wavy, rather inconspicuous, primary ridges alternating with 4 more prominent secondary ridges.

**Physical Constituents:**

- Total ash: not more than 6%
- Acid insoluble ash: not more than 1.5%
- Alcohol soluble extract: not less than 10%
- Water soluble extract: not less than 19%
- Volatile oil: not less than 0.3%.

**Chemical Constituents:**

D-mannitol, flavonoid glycosides, coriandriononediol, quercetin-3-0-caffeyl-glucoside, kaempferol 3-glucoside,, limonene, borneol, caryophyllene, thymol, geranyl acetate.

**Pharmacological Activity:**

Anti-microbial, spasmolytic.

Extract of seed shows fungitoxic effect against Helminthosporium oryzae.

Coriander sativum which was commonly used flavouring agent in food. The essential oil from coriander was found to have antibacterial activity (Silva etal, 2011). Also safety assessment of coriander showed no toxic effects (Burdock etal, 2009).
Botanical Name: *Cinnamomum verum, Presl*

Classical /Vernacular Names: கொழுப்பூலை

Natural Order: Lauraceae

Parts Used: Bark

Botanical Description:

An evergreen tree, 8-16m high, with reddish brown bark having numerous small warts.
Pharmacognosy:

Bark pieces are about 0.5 mm thick, brittle; outer surface dull yellowish-brown, marked with pale wavy longitudinal lines with occasional small scars or holes; inner surface darker in colour, striated with longitudinally elongated reticulation;

Odour fragrant; taste sweet, aromatic.

Physical Constituents:

- Total ash: not more than 3%
- Acid insoluble ash: not more than 2%
- Alcohol soluble extract: not less than 2%
- Water soluble extract: not less than 3%
- Volatile oil: not less than 1%

Chemical Constituents:

Cinnamaldehyde, eugenol, benzaldehyde, cymene, cuminic aldehyde, linalool, benzyl acetate, cinnamic aldehyde, eugenyl acetate, cinnamyl acetate, benzyl benzoate, cinnassiol Cl glucoside, cinnassiol C2 and cinnassiol C3, cinnassiol D1, its glucoside.

Pharmacological Activity:

Antimicrobial, Antiallergic, Anti-complement, Anti-Fungal, Anti-oxidant, Antinociceptive

Botanical Name: Syzygium aromatica (Linn) Merrill & Perry

Synonyms:

Eugenia caryophyllata Thunb.

Eugenia aromatica Kuntze.

Caryophyllus aromaticus Linn.
Classical/Vernacular Names:

அந்தரம், சுட்டம், காப்பிடம் கீர்மன்ப, செட்டம், கிளிளி, மஞ்சள்கற.

Natural Order: Myrtaceae

கலம்: கார்பம், மில்லீலைப்புத்தண்டு;

கம்சம்: தாம்பர்

பிரிவு: காந்திப்

கான்னக்கள்:

கி.கா. அல்லது மகாகோ. பிற்காலானாக.

கலாம்:

பிற்காலாக வசித்தார் மாத்குப்பிப்பம்

குறுக்கு கட்டியியல்களுடன்- ராத்மக

முதல்கால் காரணல்தல் திதி குறத்தம

மண்டலாக காண்பிகள் மார்னையா.

''குறுக்கு பல்லங்கள் பழிந்து பாது காற்றான்

கிறத்தாலாக உள்ள மில்லீலை-பக்தாக்கால்

நிகத்து விரோதி சிறியது விரோதின்போன்

மண்டலாக வசித்தார்கை என''

- அகத்திய கைவலாக.

• குறுக்கு மர்த்துக், மாத்தைஞ்சு கண்க் கிளாந்தைப் பொய் செய்ய.

• மில்லீலை காண்பு: அகத்திய, ராத்மக்கின் விரோதிகளாக. 
Botanical Description:

Flower buds: Greenish to pink, aromatic, clustered at the ends of branches

Parts Used: Flower buds, oil

Pharmacognosy:

Flower bud is 10-17.5mm long; dark brown/dusty red colour, consisting of a sub-cylindrical, slightly flattened, four sided hypanthium, readily exuding oil when pressed. Odour is strongly aromatic; taste pungent, aromatic followed by slight tingling of the tongue. Clusters of calcium oxalate crystals are present in stalk.

Physical constituents:

- Foreign matter: not more than 2%
- Total ash: not more than 7%
- Acid insoluble ash: not more than 1%
- Alcohol soluble extract: not less than 3%
- Water soluble extract: not less than 9%
- Volatile oil: not less than 15%

Chemical constituents:

Isobiflorin, Biflorin( Flower bud),

Eugenol, Acetyl eugenol, Eugeniin, Eugenone , Eugenol acetate, Eugenine

Eugenitone, Isoeugenitol (clove oil)

Caryophyllene, Epoxydihydrocaryophyllene, Ellagittannin- Syzyginins A, Syzyginins-B (leaves).

Pharmacological activity:

Anti-fungal, antiviral, antibacterial, cholagogue, antimicrobial, anticarcinogenic, radical scavenging activity, histamine release inhibitory activity.
Syzygium aromaticum widely used spice in food. Eugenol was found as major component in clove.

Antibacterial Activity of Eugenol: A crude MeOH extract of Syzygium aromaticum (clove) exhibited preferential growth-inhibitory activity against Gram-negative anaerobic periodontal oral pathogens, including Porphyromonas gingivalis and Prevotella intermedia. Eugenol was found to be potent bactericidal component in essential oil extracts, against fastidious and facultative anaerobic oral bacteria. Eugenol was also found that a synergistic antimicrobial effect with erythromycin.

Anti-Viral Effects: Eugenol found in clove and bay oils [Clove oil is the greatest source of eugenol (70.9% eugenol)] have virucidal effects as it is reported to inhibit herpes virus replication in vitro.

Anti-Fungal Effects: Eugenol displayed potent activity against C. albicans biofilms in vitro with low cytotoxicity and therefore has potential therapeutic implication for candidal infections.

Anaesthetic action of Eugenol: Molecular mechanism for local anesthetic action of eugenol in the trigeminal system is identified.

Antipyretic action of eugenol:The analgesic agent eugenol reduced fever when given intravenously in small doses. Eugenol was more effective in reducing fever than acetaminophen.

Antioxidant action of eugenol: Free radical scavenging activity, metal chelation and antioxidant power as shown by the higher DPPH radical scavenging activity of Cloves followed by cardamom ingredients of the trial drug Malli chooranam. Eugenol and its derivatives are responsible for potent anti-oxidant action.

Clove exerted immunomodulatory/anti-inflammatory effects by inhibiting LPS action. A possible mechanism of action probably involved the suppression of the nuclear factor-κB pathway by eugenol, since it was the major compound found in clove extract (Bachiega TH etal, 2012).
Substitutes and adulterants:

Mother of cloves, clove stems, exhausted cloves, withered cloves, clove dust containing broken stamens, farinaceous products, cereal starches, ground fruit, unripe fruits of Cinnamomum verum J. S. Presl.

The biological activity of Eugenia caryophyllata has been investigated on several microorganisms and parasites, including pathogenic bacteria, Herpes simplex and hepatitis C viruses. In addition to its antimicrobial, antioxidant, antifungal and antiviral activity, clove essential oil possesses anti-inflammatory, cytotoxic, insect repellent and anaesthetic properties.

Botanical Name: Elettaria cardamomum Linn

Classical /Vernacular Names: பார்க்கி, கார்காமம், பார்க்கி

Natural Order: Zingiberaceae

கமை: கார்கன்பெடை

காளை: கார்கன்பெடை

பிக்கி: கார்கன்பெடை

சைவீசு: இலைப்படுத்தலாகும், ஆகார்ப்பார்க்கி, பரித்துக்கல்லாம்.
Botanical Description:

Fruits trilocular, subglobose or fusiform to ovoid capsule, brownish black, angled, rugose, covered with a thin mucilaginous membrane.

Parts Used: Fruits, Seeds
**Pharmacognosy:**

Fruit: 1-2 cm long, ovoid, oblong, more or less three sided with rounded angles; greenish to pale or yellowish in colour, surface with longitudinal striations; fruit trilocular; each fruit containing about 10-15 seeds in a row of doubles. Seeds are dark brown to black, transversely wrinkled; odour strongly aromatic, taste characteristic.

Perisperm is of thin walled cells packed with rounded polyhedral starch grains and containing prismatic crystals of calcium oxalate.

**Physical Constituents:**

- Total ash: not more than 6%
- Acid insoluble ash: not more than 4%
- Alcohol soluble extract: not less than 2%
- Water soluble extract: not less than 10%
- Volatile oil: not less than 4%.

**Chemical Constituents:**

Alpha-Pinene, Sabinene, Myrecene, Limonene, Cineole, Cymene, Methyl Heptenone, Linalool, Linalyl acetate, Alpha and Beta Terpineol, Alpha- Terpinyl acetate, Borneol, Neryl acetate, Geraniol, Nerol, Neolidol, Heptacosane, Camphene, Terpinene, Alpha-Humulene.

**Pharmacological Activity:**

Anti-microbial, Analgesic, Anti-inflammatory, Anti-Fungal, Anti-Spasmodic, hepatoprotective.

Cardamom seeds are widely used for flavouring purposes in food and as carminative. A comparative study of the anti-inflammatory activity of the oil extracted from commercial Elettaria cardamomum seeds, in doses of 175 and 280 microliters/kg
and indomethacin in a dose of 30 mg/kg against acute carrageenan-induced planter oedema in male albino rats was performed, which proved to be marked. Moreover, investigation of the analgesic activity using p-benzoquinone as a chemical stimulus proved that a dose of 233 microliters/kg of the oil produced 50% protection against the writhing (stretching syndrome) induced by intraperitoneal administration of a 0.02% solution of p-benzoquinone in mice (al-Zuhair H etal, 2007)

**Substitutes and adulterants:**

Amomum subulatum Roxb. as substitute

Other common adulterants are:

- E. cardamomum var. major Thw,
- Amomum kepulaga Sprague and burkill
- Amomum korarima Periera
- Amomum aromaticum Roxb.
- Amomum xanthioides Wallich

**Botanical Name:** Nigella sativa.Linn

**Classical /Vernacular Names:** நிலை வண்ணம், டாக்ஸூட்டு

**Natural Order:** Ranunculaceae

**கால்:** கால்பா

**கல்மதி:** கல்மதி

**பிளவு:** கால்பா

**கீழ்ப்பகுதியில்:** கீழ்ப்பகுதியில், கீழ்ப்பகுதியில், கீழ்ப்பகுதியில், கீழ்ப்பகுதியில், கீழ்ப்பகுதியில், கீழ்ப்பகுதியில், கீழ்ப்பகுதியில்
Botanical Description:

Seeds trigonous, black, rugulose-tubercular.

Parts Used: seed, seed oil

Pharmacognosy:

Seeds are small dicotyledonous, trigonous, angular, rugulose-tubercular, black externally and white inside, odour slightly aromatic; taste bitter.

Physical Constituents:

- Total ash: not more than 6%
- Acid insoluble ash: not more than 0.2%
- Alcohol soluble extract: not less than 20%
- Water soluble extract: not less than 15%
- Volatile oil: not less than 0.42%.

Chemical Constituents:

esters of dehydrostearic and linoleic acid, aliphatic alcohol, carvone, d-limonene, cymene, nigellone, alkaloids, stearoids, nigellidine-indazole, alkaloid thymoquinone.
Pharmacological Activity:

Anti-microbial, Analgesic, Anti-inflammatory, Anti-Fungal, Anti-Spasmodic, hepatoprotective, Antipyretic, bronchodilator, galactogogue.

The pharmacological actions of the crude extracts of the seeds (and some of its active constituents, e.g. volatile oil and thymoquinone) that have been reported include protection against nephrotoxicity and hepatotoxicity induced by either disease or chemicals. The seeds/oil have antiinflammatory, analgesic, antipyretic, antimicrobial and antineoplastic activity. The seeds are characterized by a very low degree of toxicity. Administration of either the seed extract or its oil has been shown not to induce significant adverse effects on liver or kidney functions (Ali BH etal, 2003). Thymoquinone, as one of the major components of nigella sativa had potent analgesic and anti-inflammatory property (Hajhashemi V etal, 2004).

Botanical Name: *Vitis vinifera* Linn

Classical /Vernacular Names: வாணாக்கம், கொட்டைசிரிக்கம், மேல்கொட்டை, கொட்டைசிரிக்கம், கொட்டைக்காய், பூக்கள்

Natural Order: Vitaceae

காற்று: கொட்டைப்பூ

கொட்டை: கொட்டை

பிற்பூ: கொட்டைப்பூ

Botanical Description:

Seeds trigonous, black, rugulose-tubercular.

Parts Used: Ripe fruit (dried), leaf, stem, flower
Pharmacognosy:

Mature dried fruit, a berry, is sticky and pulpy, dark brown to black in colour, oblong or oval, sometimes spherical. Odour sweetish and pleasant; taste sweet.

Physical Constituents:

- Total ash: not more than 3%
- Acid insoluble ash: not more than 0.2%
- Alcohol soluble extract: not less than 25%
- Water soluble extract: not less than 70%

Chemical Constituents:

3-monoglucosides of delphinidin, cyaniding, petunidin, peonidin, malvidin, acetyl and coumaryl glycosides, malic acid, tannic acid

Pharmacological Activity:

Antifungal, antiulcer, hepatoprotective, antioxidant, antibacterial, antiherpetic, cardioprotective, antimutagenic.

Vitis vinifera, known as the grapevine, is native to southern Europe and Western Asia. Grape seed and skin contain several active components including flavonoids, polyphenols, anthocyanins, proanthocyanidins, procyanidines, and the stilbene derivative resveratrol. Grape seed extract in particular has been reported to possess a broad spectrum of pharmacological and therapeutic effects such as antioxidative, anti-inflammatory, and antimicrobial activities, as well as having cardioprotective, hepatoprotective, and neuroprotective effects (Nassiri-As M et al, 2009).
Botanical Name: *Glycyrrhiza glabra* Linn

Classical/Vernacular Names: ஆராசூரி, கேண்டுக்கிரீட், மல்லூர், மல்லூர்கிரீட், கேண்டுக்கீரி, வெய்தைக்காம், சுயைக்காம்

Natural Order: Fabaceae

Parts Used: Root

Pharmacognosy:

Root is yellowish brown, longitudinally wringled externally: odour is faint and characteristic: taste sweetish.

Chemical Constituents:

Glycyrrhizine, prenylated biaurone, licoargone:

7- acetoxy-2- methyl-isoflavone, glyzaglabrin, quercetin, kaempferol, astragalin, liquiritigenin and isoliquiritigenin.
Pharmacological Activity:

Anti-microbial, antiviral, hypotensive, hepatoprotective, anti-exudative, spasmylytic, antiuretic, antiulcer, antimutagenic, antipyretic, antioxidant, anti-inflammatory, expectorant.

Glycyrrhizin and liquorice extract of glycyrrhiza glabra showed anti-inflammatory action (Rackova L etal, 2007).

Botanical Name: Cuminum cyminum Linn

Classical /Vernacular Names: க்கேமி, இயூர்டைனைட்டைல், கேமிங்கன், குமினாக்சஸ், குமினுட்கு-கிஞ்சிதா, குமினாக்சுட்கா, குமினாக்சுட்க்கா, முந்தியம்

Natural Order: Umbelliferae

கணவை: காஞ்சியை, இரண்டியை

குறிப்புகள்: காஞ்சியை, இரண்டியை

பிரிவுகள்: இரண்டியை

குறிப்பிட்டு: இரண்டியை

பொருள்: இரண்டியை

குறிப்பிட்டு: இரண்டியை
Botanical Description:

The fruit is a lateral fusiform or ovoid achene 4–5 mm long, containing a single seed.

Parts Used: Fruit or seed

Chemical Constituents:

Thymene, carvone, cuminol or cumic aldehyde, cymene cymol, terpene, carvone, α-pinene, limonene, γ-terpinene, linalool, p-cymene, cuminaldehyde, limonene, α- and β-pinene, 1,8-cineole, α- and p-cymene, α- and γ-terpinene, safranal and linalool.

Pharmacological Activity:

Anti-microbial, antioxidant, antidiabetic, immunomodulator, diuretic.

Cuminum cyminum, which was used daily in food had antimicrobial action against fungi or bacteria (Zaman U et al, 2008).

Botanical Name: Carum bulbocastum Koch

Classical /Vernacular Names: பிரமொர்த்திகொம், விளைக்கொம்

Natural Order: Umbelliferae

சிற்று: சுமையு, வெள்ளியு

சிற்றுணரம்: சுமையலை

பிரிம்: வெள்ளியலை

அசியலர்கள்: அத்தியாயப்பொருள்கள், தீர்த்தியப்பொருள்கள், தொட்டியம்பொருள்கள்
Botanical Description:

The fruit is a lateral fusiform or ovoid achene 4–5 mm long, containing a single seed.

Parts Used: Fruit or seed

Chemical Constituents:

Thymene, carvone, cuminol or cumic aldehyde, cymene cymol, terpene, carvone, α-pinene, limonene, γ-terpinene, linalool, p-cymene, cuminaldehyde, limonene, α- and β-pinene, 1,8-cineole, α- and p-cymene, α- and γ-terpinene, safranal and linalool.

Pharmacological Activity:

Anti-microbial, antioxidant, antidiabetic, immunomodulator, diuretic.

A number of EO components has been identified as effective antibacterials, e.g. carvacrol, thymol, eugenol, perillaldehyde, cinnamaldehyde and cinnamic acid (Burt S, 2004).

Botanical Name: *Smilax china* Linn

Classical /Vernacular Names: பாலைக்கூறு, பாலைக்கூறு கூற், தாலைப்பாலை, பாலைப்பாலை

Natural Order: Liliaceae
Botanical Description:

Rhizome blackish externally, pale coloured or whitish internally, bitter, acrid.

Parts Used: Rhizome

Chemical Constituents:


Pharmacological Activity:

Anodyne, anti-inflammatory, digestive, laxative, depurative, aphrodisiac, diuretic, febrifuge and tonic.
4. MATERIALS AND METHODS

Virana Silethumam is one of the frequently encountered problem among young children in India. Hence it was proposed to study about the disease. A Protocol was prepared and submitted before IEC & IAEC meeting, a copy of which was attached as Annexure-I. After obtaining approval from the commitee, the study Preclinical & clinical study on Virana Silethumam (Acute Pharyngo tonsillitis) in children and the drug of choice was malli chooranam was carried out in National Institute of Siddha.

The ingredients for preparation of experimental formulation malli chooranam was purchased from a well reputed country shop and raw drugs were authenticated by Herbal botanist. The medicine was prepared in Gunapadam lab of National institute of Siddha after proper purification. The prepared medicine was also authenticated by the concerned Head Of The Dept for its completeness.

Even though the drugs were pure herb safety of Malli Chooranam by Acute Toxicity study were done in animal models according to WHO guidelines, 1993. For acute toxicity study mice were used.

After finishing the toxicity studies 40 cases were selected from the OPD & IPD of Kuzhandhai Maruthuvam Department, National Institute of Siddha. They were treated with the trial drug Malli Chooranam and observed for prognosis clinically.

STUDY DESIGN & CONDUCT OF STUDY:

Study Type: An open clinical trial

Study Place: OPD & IPD of Ayothidass pandithar hospital,

National Institute of Siddha, Tambaram sanatorium, Chennai-47.

Study Period: 12 months
Duration of trial drug: 7 days

Population and Sample:

Inclusion criteria:

- Age: 3-12 Years
- Sex: Both male & female children
- Children with symptoms of cough, sore throat, fever with malaise, swollen tonsils, odynophagia and headache.
- Patients whose parents/guardian are willing to sign the informed consent.
- Patients who are willing to attend OPD once in 7 days/admitted in IPD of Ayothissad Pandithar Hospital.
- Patients who are willing to provide blood, urine for lab investigations.

Exclusion criteria:

- Patient with known history of Primary Complex, Diphtheria/whooping Cough, Allergic Rhinitis with Post nasal drip.
- History of congenital heart disease, seizure disorders.
- Other serious illnesses based on Parental information and previous reports

Sample size was 40 patients

STUDY ENROLLMENT & CONDUCT OF THE STUDY:

Patients reporting at the OPD with the clinical symptoms of sore throat, difficulty to swallow, headache, swollen tonsils, fever and signs of diffuse congestion, lymphadenitis, exudates, petechiae, tonsillar hypertrophy were examined clinically for enrolling in the study based on the inclusion and exclusion criteria.
The patients who were enrolled and their parents were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them.

After ascertaining the patients’ willingness, informed consent was obtained in writing from their parents in the consent form (Form II).

Complete clinical history, complaints and duration, examination findings were recorded in the prescribed Proforma (Form –II). Screening Form- I was filled up; Form- IV and Form –V were used for assessment of symptoms & signs and for recording laboratory investigations respectively. Assessment were made on the basis of clinical features.

Specific investigations of ASO, CRP were done in all patients in addition to the routine blood & urine investigations, before and after treatment.

In the OPD, after initial tests and assessment, trial drug Malli Chooranam was given once for 7 days after which clinical assessment was done and prognosis noted. In cases where there is need for further treatment due to incomplete improvement, medicines were given in the regular OPD of Ayothidasss Pandithar hospital. The patients were observed for up to 14 days.

In IP, the drug was provided each day for 7 days and prognosis noted after clinical assessment done on a daily basis. Laboratory investigation was done before and after the course of the trial. At the end of the treatment, the patients were advised to visit the OPD for another two weeks for follow-up.

**ADMINISTRATION OF TRIAL DRUG:**

The drug was prepared by adhering to Standard operative procedure as per the protocol. It was dispensed in sealed polythene covers to prevent contamination. Patients were advised to take the trial drug, twice daily with milk in recommended doses (1.5 gms for 3-7 years/2.5 gms for 8-12 years). The patient compliance form was filled accordingly (Form-VII). Appropriate dietary advice (Form-IX) was given according to the patients’ perfect understanding. The patients who were defauters were withdrawn from the trial.
DATA MANAGEMENT:

After enrolling the patient in the study, a separate file for each patient was opened and all forms were filed in the file. The Data recordings were monitored for completion and adverse event.

The following ASSESSMENT FORMS were used for data collection:

- **FORM I**  SCREENING & SELECTION PROFORMA
- **FORM II**  CONSENT FORM
- **FORM III**  HISTORY PROFORMA
- **FORM IV**  CLINICAL ASSESSMENT FORM
- **FORM V**  LABORATORY INVESTIGATION FORM
- **FORM VI**  PATIENT’S INFORMATION SHEET
- **FORM VII**  WITHDRAWAL FORM
- **FORM VIII**  ADVERSE REACTION FORM
- **FORM IX**  DIETARY ADVICE FORM
5. RESULTS AND OBSERVATION

For the clinical study, 40 cases were selected and treated in Ayothidoss Pandithar Hospital of National Institute of Siddha, Chennai. Results were observed with respect to the following criteria,

1. Age distribution.
2. Gender distribution
3. Paruvam Distribution
4. Diet Habits
5. Socio – economic status
6. Family history
7. Personal habits
8. Thinai reference
9. Seasonal Reference
10. Distribution of three thodam
11. Udal kattugal reference
12. Envagai Thervugal
13. Neerkuri, Neikuri reference
14. Etiological Factors
15. Clinical features
16. Hematological investigation
17. Results after treatment.
AGE DISTRIBUTION:

<table>
<thead>
<tr>
<th>S.No</th>
<th>AGE</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3 - 8 Years</td>
<td>27</td>
<td>68%</td>
</tr>
<tr>
<td>2</td>
<td>9 - 12 Years</td>
<td>13</td>
<td>32%</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Out of the 40 cases taken for clinical trial, 27 (68%) cases were in the 3-8 years age group, 13(32%) cases were in the 9-12 years group. The doses of the drugs were given accordingly to these two groups.
GENDER DISTRIBUTION:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Sex</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>18</td>
<td>45%</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>22</td>
<td>55%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>

In the 40 cases treated, 18 (45%) were male and 22 (55%) were female.
PARUVAM DISTRIBUTION:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Paruvam</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kaappu &amp; Chenkeerai (0 – 1yr)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Varugai, Thalattu, Sappani (1- 3 yr)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Ambuli, Sitril, Chiruparai, Pethai (Female)</td>
<td>16</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td>Pillai paruvam(Male) (3 -6yrs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Paethumbai, Mangai(Female), Chiru paruvam, Vaalibam(Male) (6-12 yrs)</td>
<td>24</td>
<td>60%</td>
</tr>
</tbody>
</table>

In 40 cases, 16 cases were in the 3-6 years age group and 24 were in 6-12 age group.
**DIETARY PATTERN:**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Diet Habits</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vegetarian</td>
<td>5</td>
<td>10%</td>
</tr>
<tr>
<td>2</td>
<td>Non – Vegetarian</td>
<td>35</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Out of the 40 cases, 5(10%) cases were vegetarians and the rest 35(90%) cases had both vegetarian and non-vegetarian foods for diet.
SOCIO ECONOMIC STATUS

<table>
<thead>
<tr>
<th>S.No</th>
<th>Economic</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Poor</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>2</td>
<td>Middle class</td>
<td>28</td>
<td>70%</td>
</tr>
<tr>
<td>3</td>
<td>Rich</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>

In 40 cases, 4 were from poor, 8 from rich and the remaining 28 from middle income families.
FAMILY HISTORY:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Family History</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Present</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>2</td>
<td>Absent</td>
<td>32</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>

Out of the 40 cases, 8 cases (20%) had positive family history and the rest 32 (80%) had no family history or contacts.
PERSONAL HABITS:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Personal Habits</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nail Biting</td>
<td>28</td>
<td>70%</td>
</tr>
<tr>
<td>2</td>
<td>Thumb Sucking</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>3</td>
<td>Unhygienic Food Intake</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>4</td>
<td>Poor personal hygiene</td>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td>5</td>
<td>Nocturnal Eneuresis</td>
<td>6</td>
<td>15%</td>
</tr>
</tbody>
</table>

About 28 (70%) cases in the trial had the habit of nail biting, 12(30%) had poor personal hygiene, 8 (20%) cases had unhygienic food intake in outside eateries, 6(15%) had nocturnal enuresis.
## THINAI REFERENCE:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Thinai History</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kurinji</td>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>2</td>
<td>Mullai</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Marutham</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>4</td>
<td>Neithal</td>
<td>30</td>
<td>75%</td>
</tr>
<tr>
<td>5</td>
<td>Paalai</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

In 40 cases, 30 (75%) cases were from Neithal nilam, 8 (20%) cases were from Marutham nilam and 2 (5%) were from kurinji nilam.
SEASONAL REFERENCE:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Season</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kaarkaalam</td>
<td>19</td>
<td>47.5%</td>
</tr>
<tr>
<td>2</td>
<td>Koothirkaalam</td>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td>3</td>
<td>Munpanikaalam</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Pinpanikalaam</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>Elavenil Kalaam</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>Mudhuvenil Kaalam</td>
<td>9</td>
<td>22.5%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>

In the trial of 40 cases, majority of about 19(47.5%) cases were registered in kaarkalam, 12(30%) during koothir kalam and 9(22.5%) in mudhuvenil kalam.
DISTRIBUTION OF THREE THODAM

Table illustrating the derangement of Vatham

<table>
<thead>
<tr>
<th>S.No</th>
<th>Classification of Vatham</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pranan</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>2</td>
<td>Abanan</td>
<td>5</td>
<td>12.5%</td>
</tr>
<tr>
<td>3</td>
<td>Viyanan</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Uthanan</td>
<td>40</td>
<td>100%</td>
</tr>
<tr>
<td>5</td>
<td>Samanan</td>
<td>40</td>
<td>100%</td>
</tr>
<tr>
<td>6</td>
<td>Nagan</td>
<td>3</td>
<td>7.5%</td>
</tr>
<tr>
<td>7</td>
<td>Koorman</td>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>8</td>
<td>Kirukaran</td>
<td>5</td>
<td>12.5%</td>
</tr>
<tr>
<td>9</td>
<td>Devathathan</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>10</td>
<td>Dhananjeyan</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

In vatham, uthanan and samanan were affected in all 40 cases.

Devathathan was found to be deranged in 8 cases.
Table illustrating the derangement of Pitham:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Classification of Pitham</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Analam</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>2</td>
<td>Ranjagam</td>
<td>7</td>
<td>18%</td>
</tr>
<tr>
<td>3</td>
<td>Saathagam</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>4</td>
<td>Prasagam</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>5</td>
<td>Alosagam</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

In pitham, ranjagam was found to be affected in 8 (20%) cases and analam in 7 (18%) cases.
Table illustrating the derangement of Kabam:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Classification of Kabam</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Avalambagam</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Kilethegam</td>
<td>3</td>
<td>8%</td>
</tr>
<tr>
<td>3</td>
<td>Pothagam</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Tharpagam</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>Santhigam</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

In kabam, only klethegam was affected in 4(10%) cases out of 40 cases.
**UDAL KATTUGAL REFERENCE:**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Types</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Saaram</td>
<td>40</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>Senneer</td>
<td>16</td>
<td>40%</td>
</tr>
<tr>
<td>3</td>
<td>Oon</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>4</td>
<td>Kozhuppu</td>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>5</td>
<td>Enbu</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>6</td>
<td>Moolai</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>7</td>
<td>Sukkilam / Suronatham</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

Saaram was affected in all 40 cases, senneer in 16 (40%), oon in 4 (10%) and kozhuppu in 2 (8%) of the cases.
ENVAGAI THERVUGAL:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Types</th>
<th>No. of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Naa</td>
<td>40</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>Niram</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>Mozhi</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>4</td>
<td>Vizhi</td>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td>5</td>
<td>Sparisam</td>
<td>36</td>
<td>90%</td>
</tr>
<tr>
<td>6</td>
<td>Malam</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>7</td>
<td>Moothiram</td>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>8</td>
<td>Naadi:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Pitha kabam</td>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td></td>
<td>b. Kaba pitham</td>
<td>10</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>c. Vatha pitham</td>
<td>18</td>
<td>45%</td>
</tr>
</tbody>
</table>

Naa was affected in all 40 cases, vizhi in 12 cases, sparisam in 36 cases, mozhi, niram in 8 case each, malam in 4 cases. Vatha pitham nadi was found in 18 cases.
NEERKURI, NEIKURI REFERENCE:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Types</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NEERKURI</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaikol Niram</td>
<td>36</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Athi Manjal Niram</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>2</td>
<td>NEIKURI</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spreading like snake</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td></td>
<td>Like Ring</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>Like Pearl</td>
<td>28</td>
<td>70%</td>
</tr>
</tbody>
</table>

The urine of 36 cases (90%) were in vaikol niram, whereas 4 (10%) cases were athi manjal in colour. Kaba neer in 28 cases, pitha neer in 8 & vatha neer in 4 cases.
ETIOLOGICAL FACTORS:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Etiological factors</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Intake of cold stuffs, ice creams etc</td>
<td>18</td>
<td>45%</td>
</tr>
<tr>
<td>2</td>
<td>Drinking impure water</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>Congested dwelling places and unhygienic habits</td>
<td>10</td>
<td>25%</td>
</tr>
<tr>
<td>4</td>
<td>Familial incidence of Tonsillitis.</td>
<td>11</td>
<td>28%</td>
</tr>
<tr>
<td>5</td>
<td>Cold air exposure</td>
<td>35</td>
<td>88%</td>
</tr>
</tbody>
</table>

In etiological factors, most cases (88%) reported due to cold air exposure followed by intake of cold stuffs which was found in 45% cases.
### CLINICAL FEATURES

<table>
<thead>
<tr>
<th>S.No</th>
<th>Clinical features</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>COUGH</td>
<td>36</td>
<td>90%</td>
</tr>
<tr>
<td>2</td>
<td>FEVER</td>
<td>16</td>
<td>40%</td>
</tr>
<tr>
<td>3</td>
<td>MALAISE</td>
<td>16</td>
<td>40%</td>
</tr>
<tr>
<td>4</td>
<td>SORE THROAT</td>
<td>36</td>
<td>90%</td>
</tr>
<tr>
<td>5</td>
<td>ODYNOPHAGIA</td>
<td>32</td>
<td>80%</td>
</tr>
<tr>
<td>6</td>
<td>HEADACHE</td>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td>7</td>
<td>ANTERIOR CERVICAL LYMPHADENITIS</td>
<td>31</td>
<td>78%</td>
</tr>
<tr>
<td>8</td>
<td>DIFFUSE MUCOSAL CONGESTION</td>
<td>40</td>
<td>100%</td>
</tr>
<tr>
<td>9</td>
<td>INFLAMMATORY EXUDATES</td>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td>10</td>
<td>PETECHIAE</td>
<td>16</td>
<td>40%</td>
</tr>
<tr>
<td>11</td>
<td>PUSTULES</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>12</td>
<td>TONSILLAR HYPERTROPHY</td>
<td>36</td>
<td>90%</td>
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</table>

Cough was the predominant symptom present in 36 cases out of 40 cases.
COUGH ANALYSIS:

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<th>S.No</th>
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<th>Absent</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<tr>
<td>1</td>
<td>After Treatment</td>
<td>24</td>
<td>10</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Before Treatment</td>
<td>8</td>
<td>4</td>
<td>8</td>
<td>20</td>
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The number of cases with severe cough reduced from 20 (before treatment) to 0 (after treatment). The number of cases without cough increased from 8 to 24 after treatment.
### DISEASE PROGNOSIS:

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<tr>
<th>S.No</th>
<th>Clinical features</th>
<th>Before Treatment</th>
<th>After Treatment</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>FEVER</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>MALAISE</td>
<td>16</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>SORE THROAT</td>
<td>36</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>ODYNOPHAGIA</td>
<td>32</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>HEADACHE</td>
<td>12</td>
<td>2</td>
</tr>
</tbody>
</table>

The number of cases relieved of fever was 15 out of 16 & without malaise was 14 out of 16 and headache was 10 out of 12. All cases with sore throat and odynophagia was relieved of their symptoms.
HEMATOLOGICAL INVESTIGATION:
Erythrocyte Sedimentation rate (ESR/ hour) before treatment:

<table>
<thead>
<tr>
<th>S. No</th>
<th>ESR/hour in mm</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 and below</td>
<td>24</td>
<td>60%</td>
</tr>
<tr>
<td>2</td>
<td>11 - 20.</td>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td>3</td>
<td>21 and above</td>
<td>4</td>
<td>10%</td>
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</table>
Erythrocyte Sedimentation rate (ESR/ hour) after treatment:

<table>
<thead>
<tr>
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<th>ESR/hour in mm</th>
<th>No of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 and below</td>
<td>33</td>
<td>83%</td>
</tr>
<tr>
<td>2</td>
<td>11 - 20.</td>
<td>5</td>
<td>13%</td>
</tr>
<tr>
<td>3</td>
<td>21 and above</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>4</td>
<td>31 and above</td>
<td>1</td>
<td>3%</td>
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There is considerable reduction in groups of higher ESR and increase in groups of lower ESR, this proves the fact there is notable reduction in ESR levels on the whole.
RESULTS AFTER TREATMENT:

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<th>Results</th>
<th>No. of Cases</th>
<th>Percentage</th>
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<td>1</td>
<td>Good Relief</td>
<td>32</td>
<td>80%</td>
</tr>
<tr>
<td>2</td>
<td>Moderate Relief</td>
<td>6</td>
<td>15%</td>
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<tr>
<td>3</td>
<td>Mild Relief</td>
<td>2</td>
<td>5%</td>
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Out of the 40 cases taken for trial, 32 cases showed good relief of the symptomatology, 6 cases showed moderate relief and 2 cases showed mild relief.
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<th>CP/IP NO</th>
<th>Name</th>
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<th>AFTER TREATMENT</th>
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<td>TRBC TWBC DC</td>
<td>Hb TRBC TWBC DC</td>
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<td></td>
<td>P L E M 1/2 Hr 1 Hr</td>
<td>P L E M 1/2 Hr 1 Hr</td>
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<td>NIL EC PC</td>
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<td>R Adhiai</td>
<td>5/F</td>
<td>11.2 4.1, 8200</td>
<td>10.8 3.6 7000</td>
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<td>S Buvaneswari</td>
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</tbody>
</table>

Hb= hemoglobin in gm/dl, TRBC= Total RBC count in cells/cmm , Twbc= total wbc count in cells/cmm, DC – Differential Count P- Polymorphs, L- Lymphocyte, E- Eosinophils, M-Monocytes in %, ESR in mm/hr, ASO – Anti Streptolysin O, CRP- C reactive protein, , Alb- albumin, , EC- epithelial cells, PC- puscells, in Hpf
<table>
<thead>
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<th>CP/IP NO</th>
<th>Name</th>
<th>AGE/</th>
<th>Hb</th>
<th>TRBC</th>
<th>TWBC</th>
<th>DC</th>
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6. DISCUSSION

Virana silethumam is one of the recurrent upper respiratory tract infections seen in children due to deranged silethumam. It more or less correlates with acute Pharyngotonsillitis. The management for this disease in conventional therapy is using antibiotics or surgical procedure like tonsillectomy. Both have demerits. Hence a herbal formulation malli chooranam is taken for the study in the management of Virana silethumam.

Most of the ingredients of malli chooranam have hot, dry thanmai & kaarpu vibagam which act on deranged silethumam. Also demulcent property of the drug ingredients acting on the vitiated Pitham.

Scientifically many drug ingredient of malli chooranam have antibacterial activity. Most cause for this disease in young children is bacteria. Some drugs have antiinflammatory, analgesic, antipyretic, antioxidant properties. All these properties are beneficial for treating the illness.

Eventhough the trial drug was purely herbal origin for safety toxicity studies were done. No toxicity effect was found in the preclinical study. And also there were no adverse drug effects among trial subjects reported during or after clinical trial.

In the study 40 cases showing clinical features of Virana silethumam were admitted to trial based on the inclusion criteria. History-taking, Clinical assessment, investigations, diagnosis were done based on Siddha and modern literatures. The available data was entered into individual case proforma. The patients were treated with Malli chooranam and recommended dietary pattern. Clinical observations were made on 8th and 14th day of trial.

From the results and observations dealt in previous chapters, clinical discussions are made out.

A slight dominance (68%) in the age group of 3-8 years was observed in the study which is in accordance with the author of Pediatric otolaryngology, John Evans. In the study with 90% enrolled being non-vegetarians literature quotes excessive eating & frequent intake of sour, sweet, pungent foods as causes of excessive phlegm formation. Though over crowding, poor sanitation & malnutrition are predisposing factors only 28% of the subjects were from poor strata.
70% of the cases had nail biting and 30% did not have the habit of washing hands before eating, 20% eating unhygienic foods all predisposing to infections.

Literature states, pearl like static type of Neikuri in kaba illnesses; in the study, around 70% of the cases showed kaba neer. In line with the etiology quote in siddha texts, cold air exposure was found to be the etiology in 88% of the cases which was followed by intake of cold stuffs in 45% cases.

With reference to three thodams,
In vatham: uthanan & samanan were affected in all cases, devedhathan in 20% cases, abanan in 13% cases, and 14% showed deranged kirukaran. Nagan in 8% & koorman was affected in 5% cases each.
In pitham: ranjagam was affected in 18% cases, analam in 20% cases.
In kabam: klethagam was found to be affected in 8% cases.

The clinical features of Virana silethumam correlate with the general clinical manifestations of Acute Pharyngo-tonsillitis.

In accordance with the Clinical manifestations of Virana silethumam, sore throat was found in 90% cases, lymphadenitis accompanied with fever was present in 78% of cases, cough was the major symptom in 90% cases, difficulty in swallowing due to throat ulcer was present in 80% cases. These cases were diagnosed to have Acute Pharyngo-tonsillitis according to modern parameters.

Regarding the symptoms,
- 24 Cases were completely relieved of cough after treatment, irrespective of the severity with which they first reported. 20 cases with severe cough and expectoration before treatment had only occasional dry cough at the end of treatment.
- 16 Cases reported with fever (either intermittent or continuous), out of which 15 cases were relieved of fever at the end of course.
- 16 Cases with malaise showed improvement.
- 36 Cases with sore throat and 32 cases with odynophagia were relieved of their symptoms at the end of treatment.
All 12 Cases except two were relieved of their headache. Regarding the signs,

- Exudates in 12 cases and petechiae in 16 cases were absent at the end of trial.
- In 40 cases with diffuse congestion, 10 cases showed no congestion, 6 cases with moderate & 24 cases was with mild congestion at the end of treatment.
- During the trial, 9 cases showed severe lymphadenitis, 15 with moderate, 7 with mild lymphadenitis. At the end of the trial, 3 cases showed moderate & 21 cases with mild lymphadenitis. 16 cases had no lymphadenitis as against the earlier 9 cases before treatment.
- Reduction in tonsillar hypertrophy was not achieved to greater extent as expected. 1 case showed reduction in G₃ to G₂, 6 cases showed reduction from G₂ to G₁, 9 cases showed reduction in G₁ to G₀. Significant reduction in tonsillar size was observed only during the earlier stages such as G₁ & G₂ but not in later stages such as G₃.
- There was significant reduction in ESR in about 19 cases.

In addition, patient reported improvement in other symptoms such as constipation, stomach ache, rhinitis. Irritability and sleeplessness was relieved in younger children. The subjects’ appetite and regular bowel movements showed improvement at the end of trial. The drug improves appetite, general sleep, and controls progression of URTI to LRTI.

On basis of Siddha & Modern reasoning, improvement in the clinical features in trial subjects may be due to

- Hot, dry thanmai & kaarpu vibagam of the drug ingredients acting on the deranged Silethumam.
- Demulcent property of the drug ingredients acting on the vitiated Pitham.
- Anti-microbial activity of the Eugenol in the drug is effective against 25 genera of bacteria and virus.
- Significant anti-inflammatory, analgesic, anti-pyretic actions of the drug.
The aim of the study is to study the efficacy of Malli chooranam for the management of virana silethumam with reduction of clinical symptoms. The Siddhars with their tremendous foreseeing and unfathomable knowledge have clearly mentioned the symptomatology, etiology and treatment of Virana silethumam.

The acute toxicity study confirmed the safety of the drug and dosing among pediatric population.

For the clinical study, 40 cases were selected from Department of Kuzhanthai maruthuvam of Ayothidass Pandithar Hospital of National Institute of Siddha, Chennai. Clinical diagnosis was done by means of Siddha and Modern Methodology.

The trial subjects were treated with Malli chooranam twice daily according to the age group. Based on the reporting patients, the improvement in the condition of the patients was observed from the second day itself. Within 4 days, patient showed good relief in symptoms. Observations made during the clinical study showed that the trial drug was clinically effective.

Clinically, Malli chooranam had significant analgesic, anti-pyretic and anti-inflammatory action enough to produce clinical effects.

In clinical observation, it was found that 80% of the patients showed good relief in signs and symptoms. Further, there was no development of any adverse drug reactions in the pediatric population.
8. CONCLUSION

Clinical trial with Malli chooranam showed remarkably good results in the management of Virana silethumam without producing any adverse drug effects.

A safe herbal formulation that can be which is clinically efficacious in treating even acute inflamed conditions like acute pharyngo - tonsillitis. The drug can be safely administered to small infants in the event of recurrent episodes due to climatic changes..

Thus, it is concluded that in a developing countries like ours, the treatment with Malli chooranam will be safe, efficacious and easily available with cost effective ingredients for the welfare of pediatric population.
ANNEXURE-I

PROTOCOL

TITLE:

Preclinical & clinical study on “VIRANA SILETHUMAM” (Acute Pharyngo tonsillitis) in children and the drug of choice is MALLI CHOORANAM.

BACKGROUND:

Siddha, one of the oldest Indian Systems of Medicine aims at providing wholesome cure to all ailments a man is deposed with. It is very potent & unique when compared with other traditional systems in existence. In siddha system diseases are classified into 4448 types on basis of the three humours ie, Vatham(wind), Pitham(fire), Kabam(phlegm) constituting the fundamentals of this system. According to Classical Siddha literatures derangement of kabam can lead to 20 different types of diseases, of which Virana silethumam is one of them.

The clinical picture of virana silethumam includes sore throat with mucous and pustular exudates, swelling of anterior and posterior cervical area with fever, rigor, burning sensation all over the body, cough, crying out of severity, ulceration of throat and tongue. The symptomatology of Virana silethumam is grossly comparable with that of Acute Pharyngo-tonsillitis.

Acute Pharyngo-tonsillitis caused by Streptococcus species typically occurs in children aged 5-15 years (Chobby et al, Mar 2009). Around the world sore throat is one of the very common recurrent illnesses in children of which 37% being diagnosed as bacterial acute Pharyngo-tonsillitis.

Antibiotics kill healthy intestinal bacteria which helps to keep the immune system healthy. Also administration of antibiotics and analgesics to children may result in the development of higher resistance (Arora et al, 1999), recurrences, Reye’s syndrome, etc.. To avoid the unwanted administration of antibiotics in children which may cause many adverse effects I wish to conduct a detailed study about virana silethumam through mali chooranam, a herbal formulation.
The study drug has essential oil containing predominantly derivatives of Eugenol (Hattori et al 1986), which act potently against 25 genera of bacteria (including Streptococcus, B.subtilis) involved in causing pharyngo tonsillitis (Ghelardini et al 2007). The drugs Coriandrum sativum, Cuminum cyminum, Nigella sativa possess antibacterial activity. Glycyrrhiza glabra posses anti-inflammatory and anti-allergic activity.

**AIM & OBJECTIVES:**

Primary objective:

- To evaluate the reduction of clinical symptoms.

Secondary objective:

- To evaluate the Safety of *Malli Chooranam* in the treatment of Virana silethumam (Acute Pharyngo-Tonsillitis) through Acute and Sub acute Toxicity in animal models.
- To evaluate siddha co-factors in the course of treatment.
- To correlate between Virana silethumam and Acute Pharyngo-tonsillitis.

**MATERIALS AND METHODS**

**STUDY DESIGN & CONDUCT OF STUDY:**

**Study Type:** An open clinical trial

**Study Place:** OPD & IPD of Ayothidass pandithar hospital, National Institute of Siddha, Tamaram sanatorium, Chennai-47.

**Study Period:** 12 months
Population and Sample:

- The population consists of patients attending the OPD & IPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai-47.
- The sample consists of 3-12 years age group fulfilling the inclusion criteria.

Sample size: 40 patients

SUBJECT SELECTION:

As and when patients reporting with symptoms of inclusion criteria will be subjected to screening test & documented using screening Proforma.

INCLUSION CRITERIA:

1. Age: 3-12 Years
2. Sex: Both male & female children
3. Children with symptoms of cough, sore throat, fever with malaise, swollen tonsils, odynophagia and headache.
4. Patients whose parents/guardian are willing to sign the informed consent.
5. Patients who are willing to attend OPD once in 7 days/admitted in IPD of Ayothidass Pandithar Hospital.
6. Patients who are willing to provide blood, urine for lab investigations.

EXCLUSION CRITERIA:

- Patient with known history of Primary Complex, Diphtheria/whooping Cough, Allergic Rhinitis with Post nasal drip.
- H/O Congenital heart disease, seizure disorders.
- Other serious illnesses based on Parental information and previous reports.
WITHDRAWAL CRITERIA:

- Occurrence of serious adverse effects which may/may not be related to trial drug.
- Poor patient compliance.
- Patient turned unwilling to continue in the course of clinical trial.
- Exacerbation of symptoms

**Name of the Trial Drug: Malli Chooranam**

**STANDARD OPERATING PROCEDURE:**

**INGREDIENTS:**

1. Parangi chakkai (smilax china) – 35gms
2. Athimathuram (Glycyrrhiza glabra) – 35gms
3. Karunseeragam (Nigella sativa) – 35gms
4. Seeragam (Cuminum cyminum) – 35gms
5. Pilapu seeragam Shah-zirah (Carum bulbocastum) – 35gms
6. Elam (Elettaria cardomomum) – 35gms
7. Sannalavanga pattai (Cinnamomum verum) – 35gms
8. Kirambu (Syzygium aromaticum) – 35gms
9. Viraiilla thiraichai (Vitis vinifera) – 35gms
10. Thania (Coriandrum sativum) – 315gms
I ) SOURCE OF TRIAL MEDICINE:

The ingredients for preparation of experimental formulation MALLI CHOORANAM would be purchased from a well reputed country shop and raw drugs are authenticated by the help of Dept HOD and Herbal botanist and with Department of Gunapadam. The medicine will be prepared in Gunapadam lab of National institute of Siddha after proper purification. The prepared medicine also authenticated by the concerned Head Of The Dept for its completeness.

II ) METHOD OF PURIFICATION & PREPAREATION:

Malli Chooranam

Ref: Chikicha ratna deepam ,Pg.no. 120

PURIFICATION METHODS:

Parangisakkai: Initially the drug is dried & made into fine powder. Then milk is taken in a earthen ware vessel & its mouth is covered with cloth. Then the powder is is kept on the cloth & it is covered with another earthen ware vessel. It is then boiled for 3 hours. The resultant powder is dried in sunlight & grinded.

Athimathuram: Wash with clean water & peel the outer layer. Then cut into small pieces and dry in sunlight.

Karunjseeragam: Remove the dust & dry it in sunlight. Then fry to golden brown colour.

Seeregam: Remove the dust & dry in sunlight.

Pilappu seeragam: Dried in sunlight.

Cardamom: Dried in sunlight.

Lavangapattai :  Dried in sunlight

Kirambu :  Dried in sunlight.

Thiratchai: Remove the dust.

Kothamalli: Tie it in a cloth, and boil in hot water or lime juice. Then dry in sunlight.
Method of preparation:

All the raw drugs given above except coriander seed are fried until to golden brown colour. Then the drugs are ground into a fine powder. It is filtered by using a fine cloth (Vasthirakaayam). Now equal amount of sweet candy powder is added with the chooranam and stored in air tight container.

DOSE: Arai thola (6gms)
- 1.5 grams for 3 to 7 years of age, twice daily
- 2.5 grams for 8 to 12 years of age, twice daily

(subjected to the verification of the therapeutic dose in animal models by toxicity studies)

ADJUVANT: Milk

DRUG DURATION: 7 days


III) DRUG STORAGE:
The trial drug Malli Chooranam is stored in clean and dry wide mouthed glass bottle.

IV) DISPENSING:
The Malli chooranam is given in powder form as separate pockets of individual dose in a ziplock cover.

ASSESSMENTS & TEST:
- CLINICAL ASSESSMENT
- ROUTINE INVESTIGATION
- SPECIFIC INVESTIGATION
- SIDDHA ASSESSMENT
CLINICAL ASSESSMENT:

SYMPTOMS:

1. Cough
2. Fever, malaise and rigor
3. Sore throat with mucous and pustular exudates
4. Odynophagia
5. Headache
6. Swollen tonsils
7. Swelling of anterior and posterior cervical area lymph nodes
8. Burning sensation all over the body
9. Crying out of severity of disease.

ROUTINE INVESTIGATIONS:

BLOOD INVESTIGATIONS:

1. Haemoglobin
2. Total WBC Count
3. Differential Count
4. Total RBC count.
5. Erythrocyte Sedimentation Rate

URINE EXAMINATION:

1. Albumin
2. Deposits
SPECIFIC INVESTIGATION:

1. ASO Titre
2. CRP
3. Throat swab (if required)

SIDDHA ASSESSMENT:

1. Nilam
2. Kaalam
3. Uyirthathukal
4. Udalthathukal
5. Envagai thervu
6. Neerkuri
7. Neikuri
METHODOLOGY:

STUDY ENROLLMENT:

In the Phase II study, patients reporting at the OPD with the clinical symptoms of sore throat, odynophagia, headache, swollen tonsils, fever will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

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

After ascertaining the patients’ willingness, informed consent (Form II) would be obtained in writing from their parents in the consent form.

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

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

Patient will be advised to take the trial drug and appropriate dietary advice would be given according to the patients’ perfect understanding

CONDUCT OF THE STUDY:

The trial drug “MALLI CHOORANAM” will be given continuously for 7 days. On the 8th day patient will be requested to attend the OPD for clinical assessment and it will be recorded in the clinical assessment form and prognosis noted. The patient’s informant are requested to bring back the un-consumed trial drug if any. For IP patients the drug will be provided daily and prognosis noted. Laboratory investigations will be
done on 0 day & 15th day of the trial are recorded. After the completion of the treatment, the patient is advised to visit the OPD for another 1 months 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 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 in all forms will be monitored and scrutinized by HOD, Dept of kuzhanthai maruthuvam.

- Data analysis will be done with the help of Senior Research Officer (statistics) of NIS.

**OUTCOME:**

**PRIMARY OUTCOME:**

Will be assessed by scoring in reduction of clinical symptoms before and after treatment.

**SECONDARY OUTCOME:**

Assessed by

1. Reduction of ESR
2. Reversal of Neutrophil leucocytosis.
ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT: If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National institute of siddha and the same will be reported to regional pharmacovigilance centre.

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 will be used. There will be no infringement on the rights of patient.

3. The data collected from the patient will be kept confidentially.

4. The patient will be informed about the diagnosis, treatment and follow-up.

5. Informed consent will be obtained from the guardian of the patient after explaining in the understandable language to the patient and guardian.

6. After the consent from concerned guardian of the patient (through consent form) they will be enrolled in the study.

7. Treatment would be provided free of cost.

8. 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.

9. The patients with exclusion criteria not included in the trial will be treated as regular cases in the OPD of Ayothidass Pandithar Hospital.
ASSESSMENT FORMS

FORM I   - SCREENING & SELECTION PROFORMA

FORM II  - CONSENT FORM

FORM III - HISTORY PROFORMA

FORM IV  - CLINICAL ASSESSMENT FORM

FORM V   - LABORATORY INVESTIGATION FORM

FORM VI  - PATIENT'S INFORMATION SHEET

FORM VII - WITHDRAWAL FORM

FORM VIII - ADVERSE REACTION FORM

FORM IX  - DIETARY ADVICE FORM
ANNEXURE-II
PROFORMA

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN

FORM I - SCREENING FORM

1. SI NO:______ 2 OP/IP NO:_________ 3. NAME: _____________ 4. RELIGION: H / C / M / O
5. AGE: ______ 6.GENDER: M ☐ F ☐  7. FATHER’S OCCUPATION: _______

INCLUSION CRITERIA:

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<tr>
<td>1</td>
<td>COUGH</td>
<td>☐</td>
</tr>
<tr>
<td>2</td>
<td>FEVER</td>
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</tr>
<tr>
<td>3</td>
<td>MALAISE</td>
<td>☐</td>
</tr>
<tr>
<td>4</td>
<td>SORE THROAT</td>
<td>☐</td>
</tr>
<tr>
<td>5</td>
<td>DIFFICULTY TO SWALLOW</td>
<td>☐</td>
</tr>
<tr>
<td>6</td>
<td>HEADACHE</td>
<td>☐</td>
</tr>
<tr>
<td>7</td>
<td>SWOLLEN TONSILS</td>
<td>☐</td>
</tr>
<tr>
<td>8</td>
<td>LAB INVESTIGATIONS-WILLING</td>
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EXCLUSION CRITERIA:

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1</td>
<td>PRIMARY COMPLEX</td>
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<tr>
<td>2</td>
<td>DIPHTHERIA</td>
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<td>3</td>
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<td>4</td>
<td>ALLERGIC RHINITIS WITH POST NASAL DRIP</td>
<td>☐</td>
</tr>
<tr>
<td>5</td>
<td>OTHER SERIOUS ILLNESSES</td>
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</tbody>
</table>

ADMITTED TO TRIAL: ☐   ☐
IF YES, SERIAL NUMBER:  ☐   ☐

SIGNATURE OF INVESTIGATOR:
SIGNATURE OF LECTURER:
DATE:
FORM II - CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms readily understood by the parent.

Date:       Signature:  
Name:  

CONSENT OF THE INFORMANT:

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of the drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my son/daughter body functions.

I am aware of my right to opt out of the trial to my son/daughter at any time during the course of the trial without having to give the reasons for doing so.

I, am exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial of “Malli chooranam” in the treatment of ‘Virana Silethumam (Acute Pharyngo-tonsillitis’.

Name of the patient:  
Date:       Signature of Parent/guardian:  
Station:  
Name:  
Signature of Witness:  
Name
சின்னடையில் பொறு: சோழ கி முகம்பதை நிறுவன
அரியத்திறகை பலனை முதல்கருதுகை, 47க்க்குரிய - 47.

சுப்பர் போல்.

சுப்பர் போல்.

சுப்பர் போல்.

சுப்பர் போல்.

சுப்பர் போல்.
A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS) IN CHILDREN
FORM III - PROFORMA

1. SI NO: _____  2. OP/IP NO: _______  3. NAME: _____________  4. RELIGION: H / C / M / O
5. AGE: ______  6. GENDER: M ☐ F ☐  7. FATHER’S OCCUPATION: ___________
8. INCOME: ______  9. POSTAL ADDRESS: ______________________________________
10. INFORMANT: _______________  11. CONTACT NUMBER: __________________

12. COMPLAINTS AND DURATION:

13. HISTORY OF PRESENT ILLNESS:

14. HISTORY OF PAST ILLNESS: _________________ YES _______ NO _______
   A. JAUNDICE: ☐ ☐
   B. SEIZURES: ☐ ☐
   C. PRIMARY COMPLEX ☐ ☐
   D. CHRONIC PULMONARY DISORDER ☐ ☐
   E. DEVELOPMENTAL DELAY ☐ ☐
   F. OTHERS (PLS SPECIFY) _____________________________________________

15. FAMILY HISTORY: ☐ ☐

16. PROPER IMMUNIZATION HISTORY: ☐ ☐

17. GENERAL HABITS:
   A. NAIL BITING ☐ ☐
   B. THUMB SUCKING ☐ ☐
   C. PICA ☐ ☐
   D. UNHYGIENIC FOOD INTAKE ☐ ☐
      (ROADSIDE EATERIES)
   E. POOR PERSONAL HYGIENE ☐ ☐
   F. NOCTURNAL ENEURESIS ☐ ☐

   NORMAL ☐ AFFECTED ☐

G. APPETITE ☐ VEG ☐ NVEG ☐ MIXED _______
H. TYPE OF FOOD GIVEN: ☐ VEG ☐ NVEG ☐ MIXED _______
I. BOWELS: ☐ ☐
J. MICHTURITION: ☐ ☐
K. SLEEP ☐ ☐
18. GENERAL EXAMINATION:

A. HEIGHT (IN Cms) _____________
B. WEIGHT (IN Kgs) _____________
C. BMI: _______
D. TEMPERATURE (F) _______
E. HEART RATE _______/Min
F. PULSE RATE _______/Min
G. RESPIRATORY RATE _______/Min
H. BLOOD PRESSURE _______mm/Hg

I. PALLOR ☐ ☐
J. ICTERUS ☐ ☐
K. CYANOSIS ☐ ☐
L. CLUBBING ☐ ☐
M. LYMPHADENOPATHY ☐ ☐
N. PEDAL EDEMA ☐ ☐
O. JUGULAR VENOUS PULSATIONS ☐ ☐
P. CONGENITAL ABNORMALITIES ☐ ☐

19. CLINICAL ASSESSMENT:

A. COUGH ☐ ☐ If yes _______
B. FEVER ☐ ☐ If yes _______
C. MALAISE ☐ ☐
D. SORE THROAT ☐ ☐
E. DIFFICULTY TO SWALLOW ☐ ☐
F. HEADACHE ☐ ☐
G. ANTERIOR CERVICAL LYMPHADENITIS ☐ ☐
H. DIFFUSE MUCOSAL CONGESTION ☐ ☐
I. INFLAMMATORY EXUDATES ☐ ☐
J. PETECHIAE ☐ ☐
K. PUSTULES ☐ ☐
L. TONSILLAR HYPERTROPHY ☐ ☐ ______
M. OTHERS ________________________ ☐ ☐
20. EXAMINATION OF RESPIRATORY SYSTEM:
   INSPECTION: _______________________________________________________
   PALPATION: _______________________________________________________
   PERCUSSION: _______________________________________________________
   AUSCULTATION: _____________________________________________________

21. EXAMINATION OF OTHER SYSTEMS:
   A. CARDIOVASCULAR SYSTEM: ________________________
   B. ABDOMEN: ________________________
   C. CENTRAL NERVOUS SYSTEM: ________________________

22. OTHER ASSESSMENTS:
   A. NILAM:
      KURINJI □ MULLAI □ MARUTHAM □ NEITHAL □ PAALAI □
   B. KAALAM:
      KAAR □ KOOTHR □ MUNPANI □ PINPANI □ ILAVENIR □ MUDUVENIR □
   C. YAKKAI:
      VALI □ AZHAL □ IYAM □
      VALI AZHAL □ VALI IYAM □ AZHAL VALI □
      AZHAL IYAM □ IYA VALI □ IYA AZHAL □
   D. GUNAM:
      SATHUVAM □ RASATHAM □ THAMASAM □

   E. PORI:
      NORMAL □ AFFECTED □ PULAN: NORMAL □ AFFECTED □
      MEI □ □ UNARVU □ □
      VAAI □ □ SUVAI □ □
      KANN □ □ PAARVAI □ □
      MOOKU □ □ MOPPAM □ □
      SEVI □ □ KETTAL □ □
   F. KANMENDRIYAM:
      KAI □ □ THAANAM □ □
      KAAL □ □ KAMANAM □ □
      VAAI □ □ VASANAM □ □
      ERUVAAI □ □ VISARKAM □ □
      KARUVAAI □ □ ANANDAM □ □
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<td>NAGAN</td>
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<td><strong>2.PITHAM:</strong></td>
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<td><strong>H.UDAR THATHUKKAL</strong></td>
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<tr>
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<td>□</td>
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<tr>
<td>SUKKILAM/</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>SURONITHAM</td>
<td>□</td>
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</tbody>
</table>
### LENVAGAI THERVUGAL

**1. NAA:**
- **NIRAM:**
  - Normal: □  
  - Affected: □  
- **THANMAI:**
  - Normal: □  
  - Affected: □  
- **SUVAI:**
  - Normal: □  
  - Affected: □

**2. NIRAM:**
- Normal: □  
- Affected: □

**3. MOZHI:**
- Normal: □  
- Affected: □

**4. VIZHI:**
- **NIRAM:**
  - Normal: □  
  - Affected: □  
- **THANMAI:**
  - Normal: □  
  - Affected: □  
- **PAARVAI:**
  - Normal: □  
  - Affected: □

**5. SPARISAM:**
- □ VEPPAM  
- □ MIDHA VEPPAM  
- □ THATPAM  
- □ OTHERS

**6. MALAM:**
- **NIRAM:**
  - Normal: □  
  - Affected: □  
- **NURAI:**
  - Normal: □  
  - Affected: □  
- **IRUGAL / ILAGAL:**
  - Normal: □  
  - Affected: □  
- **EDAI:**
  - Normal: □  
  - Affected: □

**7. MOOTHIRAM:**
- **NEERKURI:**
  - **NIRAM:**
    - Normal: □  
    - Affected: □  
  - **NURAI:**
    - Normal: □  
    - Affected: □  
  - **MANAM:**
    - Normal: □  
    - Affected: □  
  - **ENJAL:**
    - Normal: □  
    - Affected: □  
  - **EDAI:**
    - Normal: □  
    - Affected: □

**NEIKURI:**
- **SERPENTINE FASHION**
  - Normal: □
- **ANNULAR/RINGED FASHION**
  - Normal: □
- **PEARL BEADED FASHION**
  - Normal: □
- **MIXED FASHION**
  - Normal: □
1. **NAADI:**

   **THANI NADI:**  
   VALI   AZHAL   IYAM

   **THONTANADI:**  
   VALI AZHAL   AZHAL VALI   AZHAL IYAM
   IYA AZHAL

   **MUKKUTRANADI**

   **THODANADI:**  
   VALI IYAM   IYA VALI

**SIGNATURE OF INVESTIGATOR:**

**SIGNATURE OF LECTURER:**

**DATE:**
A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS) IN CHILDREN

FORM V - LAB PARAMETERS CHART


<table>
<thead>
<tr>
<th>ROUTINE BLOOD INVESTIGATIONS</th>
<th>NORMAL VALUES</th>
<th>BEFORE TMT</th>
<th>AFTER TMT</th>
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<tbody>
<tr>
<td>Hb ( gms%)</td>
<td>11.5 – 14.5</td>
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<tr>
<td>T.RBC (milli /cu.mm)</td>
<td>4-4.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESR (mm)</td>
<td>½ hr. -</td>
<td>0-13</td>
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</tr>
<tr>
<td></td>
<td>1 hr.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T.WBC (milli /cu.mm)</td>
<td>5000-14500</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIFFERENTIAL COUNT (%)</td>
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</tr>
<tr>
<td>Polymorphs</td>
<td>40-75</td>
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<td>Lymphocytes</td>
<td>28-48</td>
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<td>Basophils</td>
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<td>ASO</td>
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<tr>
<th>URINE INVESTIGATION</th>
<th>Before TMT</th>
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<tr>
<td>Albumin</td>
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<td>Deposits</td>
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DATE: 
SIGNATURE OF INVESTIGATOR: 
SIGNATURE OF LECTURER:
A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS) IN CHILDREN

FORM IV - CLINICAL ASSESSMENT FORM

1. SI NO:____ 2 OP/IP NO:_________ 3. NAME: _____________ 4 . AGE: ___5.GENDER: M ☐ F ☐
6. DATE OF ADMISSION TO THE TRIAL: ☐ ☐ ☐ ☐
7. CLINICAL ASSESSMENT:

<table>
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<th>1st day</th>
<th>8th day</th>
<th>14th day</th>
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<tr>
<td>TEMPERATURE(°F)</td>
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<tr>
<td>PULSE RATE (per min)</td>
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<tr>
<td>HEART RATE (per min)</td>
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</tr>
<tr>
<td>RESPIRATORY RATE (per min)</td>
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</tr>
<tr>
<td>COUGH</td>
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<td>FEVER</td>
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<td>MALAISE</td>
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<tr>
<td>SORE THROAT</td>
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<tr>
<td>DIFFICULTY TO SWALLOW</td>
<td></td>
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<tr>
<td>HEADACHE</td>
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<td>ANT CERVICAL LYMPHADENITIS</td>
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<tr>
<td>DIFFUSE MUCOSAL CONGESTION ***</td>
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<td>INFLAMMATORY EXUDATES</td>
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<td>PETECHIAE</td>
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<td>PUSTULES</td>
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<tr>
<td>TONSILLAR HYPERTROPHY</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*** Of palate, faucial pillars, tonsil, posterior pharyngeal wall.

SIGNATURE OF INVESTIGATOR:

SIGNATURE OF LECTURER:
A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS) IN CHILDREN
FORM VII - WITHDRAWAL FORM

1. SI NO:____ 2 OP /IP NO:_________ 3. NAME: _______________ 4. AGE: __ 5. GENDER: M □ F □
6. POSTAL ADDRESS: __________________________________________________________________
_____________________________________________________________________________________

7. DATE OF ADMISSION TO TRIAL: ____________
8. DATE OF WITHDRAWAL FROM TRIAL: ____________

9. REASONS FOR WITHDRAWAL:
   - LONG ABSENCE AT REPORTING □
   - IRRREGULAR TREATMENT □
   - SHIFT OF LOCALITY □
   - INCREASE IN SEVERITY OF SYMPTOMS □
   - DEVELOPMENT OF ADVERSE DRUG REACTIONS □
   - ANY OTHER ________________________________

10. CURRENT STATUS OF THE PATIENT:
_____________________________________________________________________________________
_____________________________________________________________________________________

DATE: __________________________
SIGNATURE OF INVESTIGATOR: __________________________
SIGNATURE OF LECTURER: __________________________
A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN
FORM IX- DRUG COMPLIANCE FORM


NAME OF THE DRUG: MALLI CHOORANAM.
FORM OF THE DRUG: POWDER
ADMINISTRATION & ADJUVANT: PER ORAL, IN MILK
DOSE & DURATION: 1.5-2.5gms, TWICE DAILY FOR 7 DAYS
NO. OF DRUG PACKETS GIVEN:  ■
NO. OF DRUG PACKETS RETURNED: □

<table>
<thead>
<tr>
<th>DAY</th>
<th>DATE OF DRUG INTAKE</th>
<th>MORNING</th>
<th>EVENING</th>
</tr>
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<tbody>
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<td>DAY 1</td>
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<tr>
<td>DAY 7</td>
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SIGNATURE OF INVESTIGATOR: ________________________
SIGNATURE OF LECTURER: ___________________________
DATE: ___________________________
A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS) IN CHILDREN

FORM VIII - ADVERSE REACTION (PHARMACO-VIGILANCE) FORM

1. SI NO: ____ 2. OP/IP NO: ________ 3. NAME: ______________ 4. AGE: ____ 5. GENDER M [ ] F [ ]

6. Date of trial commencement: [ ] [ ] [ ] [ ]

7. Date of occurrence of adverse reaction: [ ] [ ] [ ] [ ]

8. Description of adverse reaction:

SIGNATURE OF INVESTIGATOR:
SIGNATURE OF LECTURER:
DATE:
கிழக்கில் குத்து காரணத்தால் விரைவாக்கம் கிழக்கில் குத்து மேலாக கருவற்று பரிபாளகத்து கிழக்கில் குத்து மேலாக கருவற்று பரிபாளகத்து

தலை படம்

என்றால் உயிரியக்காலம் குறிப்பிட்டாம் 40 போளியக்காலம்
தொண்டோல் தொண்டோல் 7 நாளில் கின்னுக்காக பைப்ல்ட்ப்பிச்சாக்காது
பெருமான் 3
நாளில் 7 போன்றானது குறைந்தவற்றில் 1.5 போன்று 8 நாளில்
குறைந்தவற்றில் 2.5 போன்று குறைந்தவற்றில் மாற்றுக்காக தரும்.

முதல் பக்காகளாக அப்படி கண்டு நிறுவக்கான படிகம் வந்துவிடுதல். முதல் பக்காகளாக அப்படி கண்டு நிறுவக்கான படிகம் வந்துவிடுதல். இந்தப் பக்காகளா

பாதுகாக்கும் பாதுகாப்பு

முதல் குறிப்பிட்டாத பாதுகாப்பு உள்ளது பாதுகாப்பு செய்யல் முதல்

குறைந்தவற்றில் குறைந்தவற்றில் முதல் குறைந்தவற்றில் குறைந்தவற்றில்

குறைந்தவற்றில் குறைந்தவற்றில் குறைந்தவற்றில் முதல் குறைந்தவற்றில்

தொண்டோல் 7 நாளில் கின்னுக்காக பைப்ல்ட்ப்பிச்சாக்காது

நாளில் 7 போன்றானது குறைந்தவற்றில் 1.5 போன்று 8 நாளில்

குறைந்தவற்றில் 2.5 போன்று குறைந்தவற்றில் மாற்றுக்காக தரும்.

சிலையூர் குப்பை குட்டியின் கத்தையிறக்காலம் குறிப்பிட்டாம் 9894765816 கனவு கருத்தின் நிறுவன நிறுவனம்.

சிலையூர் குப்பை குட்டியின் கத்தையிறக்காலம் குறிப்பிட்டாம் 9894765816 கனவு கருத்தின் நிறுவன நிறுவனம்.
INFORMATION SHEET regarding the clinical research of the therapeutic benefits of Siddha drug MALLI CHOORANAM in treating VIRANA SILETHUMAM.

Principal investigator: Dr.A.RENUGA  
Place of study: National Institute of Siddha, Chennai-47.

In this 1 year study, 40 patients are to be treated for 7 days. The drug would be dispensed to the patients in doses of 1.5gms (3-7 years of age) and 2.5gms (in 8-12 years of age).

Through this study a safe, cost effective and reliable drug for throat infection can be made known to the world. There will be no risk of physical, psychological or professional means, by taking part in this study. Information of your son/daughter will be kept confidential.

In the event of development of any other illness, he/she will be treated in OPD/IPD of the hospital. The herbal medicine will not cause any risk to his/her life or health condition. You can wish not to take part or withdraw from the study at any time out of your own free will.

If you agree to make your son/daughter a participant in the study, blood (2ml) and urine investigations will be carried out on the before and after treatment to monitor health status. The medicine and investigations are free of cost.

If you wish to find out more about this study, you can contact Dr.A.RENUGA, PG Scholar cum Principal Investigator of the study through mobile number 9894765816.

The drug MALLI CHOORANAM as stated in Chickicha ratna deepam, consists of coriander seeds, clove, elaichi and other ingredients with the property of healing throat infections.

Your son/daughter will be made a participant in this study, primarily after you sign the consent form on account of wishing to enroll him/her.
ANNEXURE-3

PREPARATION OF TRIAL MEDICINE

Malli Chooranam

INGREDIENTS:

1. Parangi chakkai (smilax china)
2. Athimathuram (Glycyrrhiza glabra)
3. Karunseeragam (Nigella sativa)
4. Seeragam (Cuminum cyminum)
5. Pilapu seeragam Shah-zirah (Carum bulbocastum)
6. Elam (Elettaria cardomomum)
7. Sannalavanga pattai (Cinnamomum verum)
8. Kirambu (Syzygium aromaticum)
9. Viraiilla thiraichai (Vitis vinifera)
10. Thania (Coriandrum sativum)

Ref: Chikicha ratna deepam, Pg.no. 120

Method of preparation:

All the raw drugs given above except coriander seed are fried until golden brown colour. Then the drugs are ground into a fine powder. It is filtered by using a fine cloth (Vasthirakaayam). Now equal amount of sweet candy powder is added with the chooranam and stored in air tight container.

DOSE: Arai thola (6gms)

- 1.5 grams for 3 to 7 years of age, twice daily
- 2.5 grams for 8 to 12 years of age, twice daily

ADJUVANT: Milk

DRUG DURATION: 7 days

INDICATIONS: Thondaipun, Thondaikammal, Vikkal, Vaanthi, Kaatthadaippu

Arosikam, Athika viyarvai viduthal, Kaikaal erichal.
Nigella sativa

Glycyrrhiza glabra

Smilax china

Vitis vinifera
ACUTE TOXICITY STUDY OF MALLI CHOORANAM

[WHO guidelines, 1993]

Principle:

Acute toxicity was carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound the study duration will be 14 days.

Animal species : Swiss albino mice
Age / Weight / Size : 6 weeks. Mice-20-25 gms.
Gender : Both male and female
Number of Animals : Mice: 10
Acclimatization Period : 7 Days
Clinical dose : 5.0 gms/day

<table>
<thead>
<tr>
<th>S.No</th>
<th>Group</th>
<th>No of mice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vehicle control (saline)</td>
<td>10 (5 male, 5 female)</td>
</tr>
<tr>
<td>2</td>
<td>Toxic dose</td>
<td>10 (5 male, 5 female)</td>
</tr>
<tr>
<td></td>
<td>10X therapeutic dose (54mg)</td>
<td></td>
</tr>
</tbody>
</table>

Test Animals

Test animals were obtained from the animal laboratory of the King institute, Chennai and stocked at National institute of siddha, Chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c). The animals had free access to water
and standard pellet diet (Sai Durga foods pvt.ltd, Bangalore). The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. (1248/ac/09/CPCSEA/February/ 2012)

**Route of administration:**

Oral route was selected, because it is the normal route of clinical administration.

**Test substance and vehicle**

Malli Chooranam is light greenish yellow in colour. The test substance is insoluble in water, in order to obtain and ensure the uniformity in drug distribution the drug is dissolved by aqueous Tween 80 solution (30%).

**Administration of doses**

Malli Chooranam was suspended in aqueous Tween 80 solution (30%), with uniform mixing and it was administered to the groups in a single oral dose. The control groups were received equal volume of the vehicle. The animals were weighed before giving the drug. The dose level was calculated according to body weight, and surface area. Since the clinical dose was 3.0gms\day it was converted to animal dose (54mg) and then administered. The principle of laboratory animal care was followed.

**Observations**

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration. The animals were monitored for behavioural parameters like

1. Awareness
   - Alertness
   - Visual placing
   - Stereotype
   - Passivity

2. Mood
   - Grooming
- Restlessness
- Irritability
- Fearfulness

3. Motor activity

- Spontaneous activity
- Reactivity
- Touch response
- Pain response.

Animals were observed for body weight and mortality for 14 days. If animals died during the period of study, the animals were sacrificed. At the end of the 14th day all animals were sacrificed and necropsy was done.

**Body Weight**

Individual weight of animals was determined before the test substance was administered and daily for 14 days. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and sacrificed.

**Results:**

Malli Chooranam at the dose 54mg/animal did not exhibit any mortality in mice.

No behavior changes were noted for the first 4 hours and for the next 24 hours and throughout the study period of 14 days. No weight reduction was noted before and after the acute study duration. Reflexes were found to be normal before and after the study. All other observations were found to be normal before and after the study. In Necropsy, the organs of the animal such as, Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.
ANNEXURE-5

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NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation Malli Choornam (Internal) for the treatment of Virana Silethumam (Acute Pharyngo tonsillitis) taken up for Post Graduation Dissertation studies by Dr. A. Renuga, M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2011-12, are identified and authenticated through Visual inspection / Experience, Education & Training/ Organoleptic characters/ Morphology / Micromorphology / Taxonomical/ Microscopical methods.

Smilax china Linn. (Liliaceae), Root
Glycyrrhiza glabra Linn. (Fabaceae), Root
Nigella sativa Linn. (Renunculaceae), Seed
Cuminum cyminum Linn. (Apiaceae), Fruit
Carum bulbocastanum Koch. (Apiaceae), Fruit
Elettaria cardamomum Maton (Zingiberaceae), Fruit
Chimnanunnum verum Presl. (Lauraceae), Stem Bark
Syzygium aromaticum (Linn ) Merr. & L M. Perry (Myrtaceae), Flower bud
Vitis vinifera Linn. (Vitaceae), Dried fruit
Coriandrum sativum Linn. (Apiaceae), Fruit

Certificate No. NIS/MB/52/2012

Date: 12-3-12

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

This is certify that the project title "Preclinical & Clinical Study on Vizama Sulfa Dieum (Acute Pharyngotonsillitis) in Children and the Drug of Choice is Hallic Chorxanam" has been approved by the IAEC.

Prof. Dr. K. Manickavasakam
Name of Chairman/Member Secretary IAEC:

Dr. B. Jayachandran Jare
Name of CPCSEA nominee:

Signature with date

Chairman/Member Secretary of IAEC:

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)
Name: A. Renuka, Reg. No.: 33102705
Title: Preclinical & Clinical Study on Viral Sore Throat (Acute Pharyngotonsillitis) in Children and the Drug of Choice is Haldi Chooranam.

DEGENCY

Opinion of the Institutional Ethics Committee – Please Check one

- [ ] Approval
- [ ] Modifications required prior to approval (Please specify one space below)
- [ ] Disapproval

Date of review: 
Signed: [Please print name] Dr. V. Subramanian

(Please decide as appropriate, Chairperson, Secretary)

Modifications needed

Modification given to candidate

The research proponent is hereby informed that the Institutional Ethics Committee will require the following:

1. All adverse drug reactions (ADRs) that are both serious and unexpected to be reported promptly to the IEC within 7 working days
2. The progress report to be submitted to the IEC at least annually
3. Upon completion of the study, a final study status report needs to submitted to the IEC