CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

AN OPEN LABELED CLINICAL TRIAL ON PEENISAM (SINUSITIS)

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I. BACKGROUND

Sinusitis and Significance:

Of all the respiratory infections, sinusitis is one of the most common illnesses that affect a high proportion of the population. According to the National Ambulatory Medical Care Survey data, sinusitis is the fifth most common diagnosis for which an antibiotic is prescribed. In 2004 a survey conducted by United States Census Bureau on prevalence of sinusitis worldwide reported country wise statistics on the sinusitis prevalence. The prevalence of sinusitis in India is 12.8%

Sinusitis refers to an inflammatory condition involving the four-paired structures surrounding the nasal cavities. Although most cases of sinusitis involve more than one sinus, the maxillary sinus is most commonly observed. Normally, mucus does not accumulate or remain sterile in the sinuses. When the sinus ostia are obstructed or when ciliary clearance is impaired or absent, the secretions can be retained producing the typical signs and symptoms of sinusitis. The retained secretions may become infected with a variety of pathogens, including viruses, bacteria and fungi.

In 1996, the American Academy of Otolaryngology-Head & Neck Surgery multidisciplinary Rhinosinusitis Task Force (RTF) defined adult rhinosinusitis diagnostic criteria. Major factors included facial pain or pressure, nasal obstruction or blockage, nasal discharge or purulence or discolored postnasal discharge, hyposmia or anosmia, purulence in nasal cavity, and fever. In 2003, the RTF's definition was amended to require confirmatory radiographic or nasal endoscopic or physical examination findings in addition to suggestive history.

Current thinking supports that chronic rhinosinusitis (CRS) is predominantly a multifactorial inflammatory disease. Confounding factors that may contribute to inflammation include the following:

- Persistent infection (including biofilms and osteitis)
- Allergy and other immunologic disorders
- Intrinsic factors of the upper airway
- Super antigens
- Colonizing fungi that induce and sustain eosinophilic inflammation

Medical therapy is directed toward controlling predisposing factors, treating concomitant infections, reducing edema of sinus tissues, and facilitating the drainage of sinus secretions. The goal in surgical treatment is to reestablish sinus ventilation and to correct mucosal opposition in order to restore the mucociliary clearance system. Surgery strives to restore the functional integrity of the inflamed mucosal lining.

As the antibiotics and surgeries done for the chronic rhino sinusitis (CRS) have failed in curing the chronic sinusitis, there is a need for herbal drugs which will give effective remedy. Major hindrance in amalgamation of herbal medicines in modern medical practices is lack of scientific and clinical data proving their efficacy and safety. There is a need for conducting clinical research in herbal and herbo-mineral drugs, developing simple bioassays for biological standardization, pharmacological and toxicological evaluation and developing various animal models for toxicity and safety evaluation. It is also important to establish the active components from these plant extracts. There are many herbal remedies suggested for sinusitis in Siddha. Moreover metallic preparations are indicated for chronic sinusitis in Siddha. With a view to help the suffering community there is a need to find a safer, cost effective drug which could cure the disease without surgical intervention and can be used safely for longer periods.

SINUSITIS IN SIDDHA:

The disease is also called dropsy, running nose or nasal mucous discharge (Peenisam). The essential features of the disease are:

Congestion in the nostrils and eyes, running nose and eyes, sneezing, headache, frequent blowing of the nose with discharge of sputum, pus and blood.

Aetiopathogenesis:

The disease may be caused by the following factors:

1. Drinking chilled water, exposure to mist and chill air, allergy to smoke, inhalation of dusty air.
2. Taking head bath in cold water and eating foods which will produce cooling effect when the body is hot.
3. The disease may also arise as an associated feature of venereal disease.
4. It is also considered that while practicing yoga, the body heat may become excess and will spread up to head and brain and cause the disease.

Prodromal symptoms:

There may be burning sensation of the nose with itching. In view of this, the patient may rub the tip of the nose and the nose will be congested. There will be also congestion of the eyes with discharge of tears. The speech will be also impaired as if the nose is blocked. There may be a sensation of block in the ears with itching of ears. In addition there will be excessive involuntary discharge from the nose like ice water.

Types of the disease:

It is considered by some as the disease is of 86 types. Some other considers that the disease is of 18 types. But the ancient Tamil authors have classified it into 9 types which is generally followed. The 9 types are:

1. Vali Mookkadaippu (Vali nasal block)
2. Azhal Mookkadaippu (Azhal nasal block)
3. Iyya Mookkadaippu (Iyya nasal block)
4. Neer Mookkadaippu (Water nasal block)
5. Kurudhi Mookkadaippu (Blood nasal block)
6. Sel Mookkadaippu (Pus nasal block)
7. Sirai Mookkadaippu (Lower nasal block)
8. Mulai Mookkadaippu (polyp nasal block)
9. Kaluthu Mookkadaippu (Neck nasal block)

Treatment:

In this disease, it is better to treat the ulcers of the nose and cure the disease rather than controlling the aggravating of Pitham and Kabam. The treatment consists of applying snuff powder, nasal drops and inhalation of the smoke, there by bringing out the sputum. In addition, medicines are given internally to control the Kaba Dosha and oil baths are taken to control the heat which attacks the skull.

II. AIM

To study the clinical efficacy and drug safety of the Siddha formulation on Peenisam (Chronic frontal & maxillary sinusitis)

OBJECTIVES:

A. Primary :

To study the clinical efficacy of APNC on Peenisam

B. Secondary:

1. Assessment of the drug safety of APNC in Peenisam
2. To study the effect of APNC in different types of Udal Vagu (Body constitution) mentioned in Siddha. (on the basis of generated data)
3. To validate the Kuttram verupadugal (Pathophysiology) of Peenisam mentioned in Siddha. (on the basis of generated data)

III. CENTRE

Identified centers of CCRS

IV. SAMPLE SIZE AND METHODS

Sample size	:	30 cases in each center
Trial period	:	6 months
Design of the study	:	Open labeled clinical trial, OPD level
Drug & dosage	:	APNC 1 cap b.i.d
Duration of medication	:	42 days drug therapy with a follow up for 15 days without drug.
Total study period	:	1 year to complete study.
Follow - up	:	The follow-up study will be carried out after 15 days of treatment.

V. SOURCE OF PROCUREMENT OF DRUG

Central Council for Research in Siddha (SCRI, Chennai)

VI. TREATMENT

A. Dietary regimen:

1. **Avoid dietary items which increase the Iyam such as poosani, peerkku, pudal, Surai Etc...**
2. **Avoid chilled water, exposure to mist & chill air**

B. Trial drug:

1. APNC (coded drug) twice a day, half an hour before meals for 6 weeks.

Diet: - Patients will be advised to take their diet as described in Patient information sheet.

VII. CRITERIA FOR INCLUSION

1. Age between 18 - 60 years
2. Rhinorrhea
3. Redness & lacrimation of the eyes
4. Nasal congestion
5. Nasal Speech
6. Itching & blockage of ears
7. Difficulty in breathing
8. Head ache
9. Post-nasal drip
10. Giddiness
11. Dull ache in mid face or deep into eyes
12. Sneezing
13. Chronic hyperplastic Sinusitis (Nasal polyp)
14. Deviated Nasal Septum (DNS)
15. X Ray PNS - Sinusitis - Positive

VIII. CRITERIA FOR EXCLUSION

1. Bacteremia /Glaucoma/Trachoma
2. Meningitis /Aneurysms of arteries of brain
3. Acute Pyrexia/SOL
4. Habitual snuffer
5. Epistaxis / Saddle nose / Syphilitic chancre
6. DM/Thyroid/HT/Trigeminal Neuralgia/Dental caries
7. Hansen's Disease
8. Bronchial Asthma

IX. CRITERIA FOR WITHDRAWAL: -

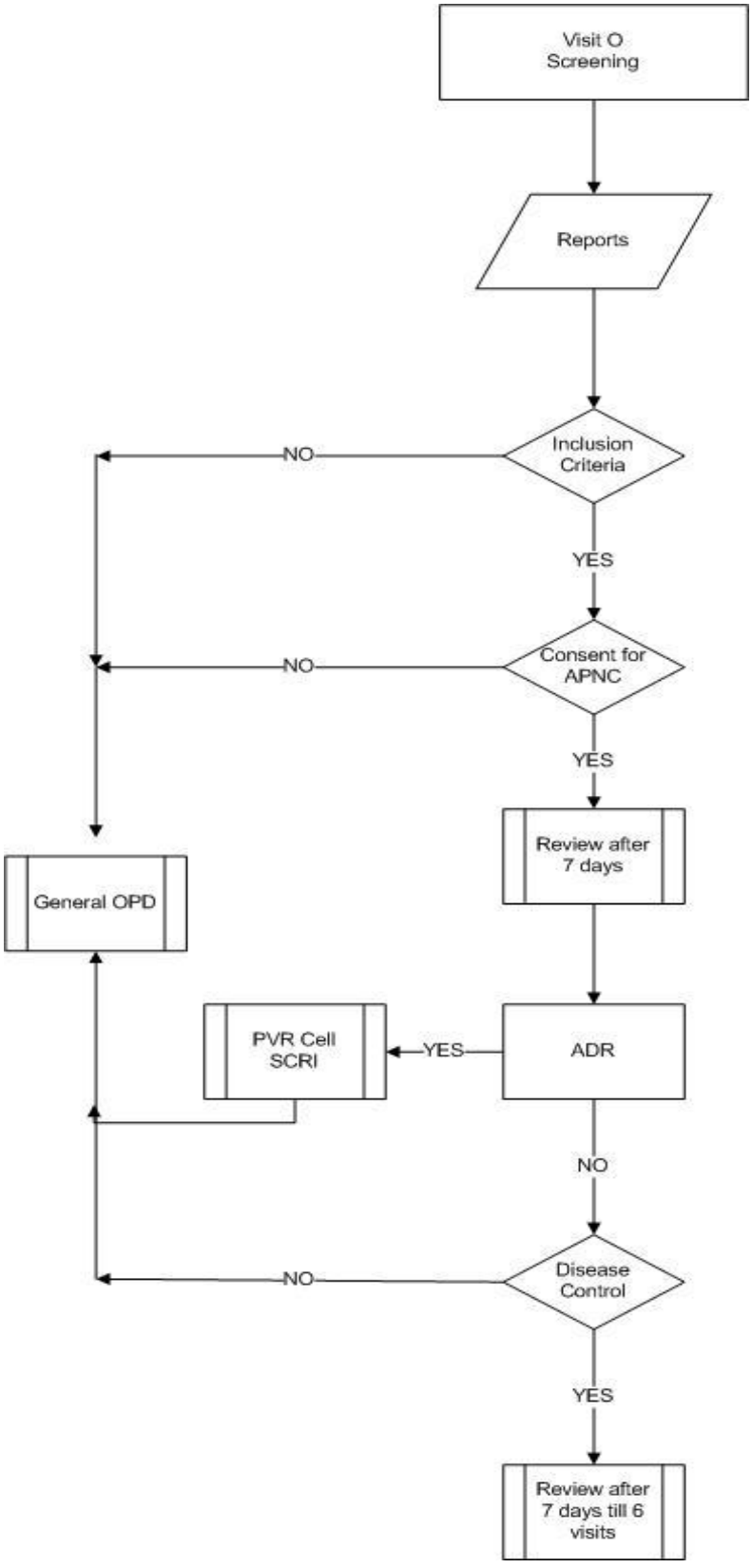
1. The investigator shall withdraw the patients from the study if they develop any or more of the following diseases:

A. Persistent dysponea.
B. Meningitis
C. Bronchial Asthma
D. Eye-lid abscess
E. Aneurysms or infected blood clots in the cavernous sinus and carotid artery
F. Anosmia & dysgyusia

2. Any serious complication develops which requires urgent treatment with any other Drug/therapy.

The investigator will mention the probable cause of withdrawal and provide possible medical treatment to manage the illness.

Study design



X. ROUTINE EXAMINATION AND ASSESSMENT

The full details of history and physical examination of the patients will be recorded as per the proforma (Forms I & IA). Clinical and physiological assessment will be done before drug administration and after every week. The laboratory investigations will be recorded before drug administration (Form-III) and at the end of treatment (Form-III)

XI. CRITERIA FOR SUCCESS OF TREATMENT

Treatment outcome as assessed by the patient and the investigator on the 'Integrated Medicine Outcomes Scale' (IMOS), a five point verbal rating scale with the categories 'complete recovery', 'major improvement', 'slight to moderate improvement', 'no change' and 'deterioration.

XII. STATISTICAL ANALYSIS

Data on Sinusitis Severity Score (SSS), Clinical improvement by IMOS and AEC, IgE and X-ray findings will be analyzed by using appropriate statistical methods.

XIII. TRIAL MONITORING AND DATA ANALYSES

The progress of the trial will be monitored by CCRS Head Quarters, New Delhi consisting of one expert each from Allopathy and Siddha besides one outside expert. Data analysis will be undertaken at SCRI, Chennai.

XIV. ETHICAL REVIEW

Institutional Ethical Committee (IEC) of participating center should give clearance certificate before the project is initiated. Patient's information sheet and informed consent form should be submitted along with project proposal for approval by IEC. Both should be maintained in duplicate with one copy given to the patient at the time of entry to the trial.

References

- P Van Cauwenberge, J B Watelet., Epidemiology of chronic rhinosinusitis *Thorax* 2000;**55** (Suppl 2):S20–S21

- Maragalavatha., et.al , clinical trial of Srilankan traditional decoction of pitawakka navaya in the treatment of kaphaja shirsha soola., www. ayujournal.org

- Arish M.K Sherwani, et.al Nazla – A Well Understood Phenomenon of Arabs,Misinterpreted by Successors, JISHIM, 2006, 5

- Claus Bachert1,et.al ,Treatment of acute rhino sinusitis with the preparation from Pelargonium sidoides EPs 7630: A randomized, double-blind, placebo-controlled trial, Rhinology,47, 51-58, 2009.

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PEENISAM (SINUSITIS)
CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms easily understood by the patient.

Date: _____ Signature_____

Name_____

CONSENT BY SUBJECT

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

I have been informed about the possible side effects and procedures to report when encountered. I am also aware of my right to opt out of the trial at any time during the course of the trial without having to give reasons for doing so.

I, exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial on "Open labeled clinical trial on Peenisam (Sinusitis) with the drug APNC.

Date: _____ Name of the Subject: _____

Signature or Thumb impression_____

Date: _____ Name of witness: _____

Signature or Thumb impression: _____

Relationship _____

Translate in to regional Language

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

OPEN LABELED CLINICAL TRIAL ON
PEENISAM (SINUSITIS)

PATIENT INFORMATION SHEET

STUDY DOCTOR:

SITE OF INVESTIGATION:

CONTACT No:

You are being asked to participate in a clinical research study. However, before you decide to be a part in this study, you need to understand the risks and benefits as well as what is expected of you as a study participant. Please read the following information carefully. This consent form may contain word (s) that you do not understand. Do not hesitate to ask the doctor and/or doctor's staff any questions you may have. You should not sign this form until you understand all the information presented in the following pages and until all your questions about the research have been answered to your satisfaction.

What is the study about?

Research is going on to find a suitable natural product for the treatment of Sinusitis. You are invited to participate in such a study in which you will receive Siddha trial drug.

The aim of the present study is to clinically evaluate APNC

Totally 30 patients from this hospital will be taking part in this study.

What will you have to do?

Your doctor will explain clearly what you have to do. It is important that you follow the instructions scrupulously. The study will take approximately 6 weeks to complete. After this period, you are expected to visit the hospital every fortnight. The interval between the first and the second visit will be around 14 days.

Before you start treatment, during the first visit to the clinic, you will undergo a complete physical examination X ray will be taken and analyzes of blood and urine samples will be done. This is to make sure that you are eligible for the study.

One week later, at your second visit, if you are eligible, you would be put on trial treatment for 6 weeks. You may receive trial drug for 6 weeks. You should follow life style modifications (Diet, Exercise etc.) as given along with information Sheet.

Blood samples will be taken at every visit. At each visit, you will be supplied with sufficient quantity of drug to last until your next visit.

What happens at the end of the study?

The trial treatment will be stopped at the end of **6 weeks**. You will be referred to the General OPD.

Are there any risks?

During the trial if you encounter any one of the following problems you should report immediately to the study doctor.

Persistent dysponea, meningitis, bronchial asthma, eye lid abscess and anosmia.

What are the alternatives?

Your doctor will be pleased to explain to you the available alternative treatment for Sinusitis

When can you leave the study?

Your participation in the study is entirely voluntary. You can choose to leave the study at any time. Your decision to leave the study will not affect your medical care or relationship with your doctor.

Your doctor may decide that you should not continue in the study if you develop any of the following conditions:

Persistent dysponea

Meningitis

Bronchial asthma

Eye lid abscess

aneurysms or infected blood clots in the cavernous sinus and carotid artery

Anosmia

What is the cost of the study?

All medication and tests to be done during the study will be free of charge.

If you do not want to participate, you are free to do so. It will not affect your medical care or relationship with your doctor in any way.

What happens now if you decide to take part?

You will be asked to sign a consent form saying that you have been given information about the study and you voluntarily agree to take part.

It is important to follow carefully all the instructions given by your doctor or doctor's assistant.

What about the confidentiality?

The study data in your name or address will be coded with initials and number in your records. The confidentiality will be maintained. Unless required by law, only the Study Doctor, the Study Team and its authorized agents and the members of the Institutional Ethics Committee will have access to the confidential data which identifies you by name.

Any other additional information of this trial:

If you have any questions regarding the research study or if you need emergency medical treatment while you are participating in this study, or have questions or additional concerns about the study, you should contact the study doctor

Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Translate in to regional Language

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

OPEN LABELED CLINICAL TRIAL OF APNC IN PEENISAM (SINUSITIS)

CASE RECORD FORM I – SCREENING

BEFORE TREATMENT

1. Code No (of clinical trial) ☐

2. Center

3. Name of the subject Mr/Ms/Mrs. ----------

4. Serial no of the subject ☐☐☐☐

5. Gender Male ☐ **Female** ☐

6. Date of Birth ☐☐☐ **Age _____ years**

7. Address: Permanent postal address with phone number /e-mail if any

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---------- ☐☐☐☐☐☐

_____

Mobile: ☐☐☐☐☐☐☐☐☐☐ **Phone no:** ☐☐☐☐☐☐☐☐

	Yes (1)	**No (2)**
CRITERIA FOR INCLUSION		
8. Age between 18 - 60 years	☐	☐
9. Head ache	☐	☐
	☐	☐

10. Nasal congestion

11. Dull ache in mid face or deep into eyes ☐ ☐

12. X Ray PNS - Sinusitis (+ve = Yes, -ve = No) ☐ ☐

13. Rhinorrhea ☐ ☐

14. Redness & lacrimation of the eyes ☐ ☐

15. Nasal speech ☐ ☐

16. Itching & blockage of ears ☐ ☐

17. Difficulty in breathing ☐ ☐

18. Post-nasal drip ☐ ☐

19. Giddiness ☐ ☐

20. Sneezing ☐ ☐

21. Chronic hyperplastic sinusitis (Nasal polyp) ☐ ☐

22. Deviated Nasal Septum (DNS) ☐ ☐

Exclusion criteria	**Yes (1)**	**No (2)**
23. Age more than 60 years and below 18 years	☐	☐
24. Bacteremia / Glaucoma/Trachoma	☐	☐
25. Meningitis /Aneurysms of arteries of brain	☐	☐
26. Acute Pyrexia/SOL	☐	☐
27. Habitual snuffer	☐	☐
28. Epistaxis / Saddle nose / Syphilitic chancre	☐	☐
29. DM/Thyroid/HT/Trigeminal Neuralgia/Dental caries	☐	☐
30. Hansen's Disease	☐	☐

A subject is eligible for admission if 'yes' is the answer for Q.No-8 to 22 (Compulsory 1 & 12) and 'No' is the answer for Q.No-23 to 30.

Date: _____ Signature of investigator: _____

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CASE RECORD FORM II – HISTORY

BEFORE TREATMENT

1. Code No (of clinical trial) ☐

2. Center

3. Serial No of the subject ☐☐☐☐

3. Name of the subject Mr/Ms/Mrs. ----------

5. Gender Male ☐ **Female** ☐

6. Date of Birth ☐☐☐ **Age _____ years**

7. Address: Permanent postal address with phone number /e mail if any

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8 .Educational status: (ENTER √ IN THE APPROPRIATE BOX)

Illiterate		**Matriculation**		**Graduate**		**Post graduate**	

9. Annual income : ☐ 60,000 (enter ≤, ≥)

10. Occupation : Exposure to Chemicals ☐ **Exposure to fumes** ☐

Exposure to polluted Environment ☐ **Perfume industry** ☐

☐ ☐

Coal mines **Cement industry**

Others if any _____

11. History of present illness:	**Sudden**	**Gradual**
1. Onset	☐	☐

2. Duration of symptoms _____ **days/month/years**

12. Signs and Symptoms	**Present**	**Absent**
1. Itching & burning sensation in the nose.	☐	☐
2. Profuse watery discharge from the nose.	☐	☐
3. Redness & lacrimation of the eyes.	☐	☐
4. Nasal speech.	☐	☐
5. Itching & blockage of ears.	☐	☐
6. Heaviness of the Head.	☐	☐
7. Difficulty in breathing.	☐	☐
8. Head ache	☐	☐
9. Nasal congestion	☐	☐
10. Post nasal drip	☐	☐
11. Dull ache in mid face or deep into eyes	☐	☐
12. Sneezing	☐	☐
13. Giddiness	☐	☐

13. Triggering factors:	**Aggravated**	**Not Aggravated**
1. Exposure to dust/ fumes & fog	☐	☐
2. Cold exposure	☐	☐
	☐	☐

3. Exposure to irritating & aromatic substance.

4. Eating cold food materials. ☐ ☐

5. Drinking cold & contaminated water. ☐ ☐

14. Family History	**Yes (1)**	**No (2)**
Hereditary pre disposal	☐	☐
Bronchial asthma	☐	☐
Allergic disorders	☐	☐

15. Personal history: **Yes (1)** **No (2)**

- **Smoking** ☐ ☐

Quantity (Packs) _____/day Total duration in years_____

- **Alcoholic** ☐ ☐

Quantity (ml) _____/day Total duration in years_____

- **Non-vegetarian diet** ☐ ☐

16. Udaliyal

Vatham ☐ **Pitham** ☐ **Kabam** ☐

17. Physical examination

1. **Body Weight _____ Kg**
2. **Height _____ Cm**
3. **BMI _____**
4. **Temperature _____$^{o}_{F}$**
5. **Blood Pressure _____mm Hg**

6. **Pulse rate _____ /min**

7. **Respiratory rate_____/min**

8. **Nasal examination for polyp / deviation of septu** ☐ ☐

9. **Pallor** ☐ ☐

10. **Jaundice** ☐ ☐

11. **Koilonychia** ☐ ☐

12. **Lymphadenopathy** ☐ ☐

SIDDHA ASPECTS

25. KAALA NILAI

1. Kaarkaalam ☐ 2.Koothirkaalam ☐ 3. Munpanikaalam ☐

4. Pinpanikaalam ☐ 5.Ilavenirkaalam ☐ 6.Muduvenirkaalam ☐

AYMPORIGAL	NORMAL (1)	AFFECTED (2)	
27. Mei	☐	☐	_____
28. Vaai	☐	☐	_____
29. Kan	☐	☐	_____
30. Mookku	☐	☐	_____
31. Sevi	☐	☐	_____

AYMPULANGAL	NORMAL (1)	AFFECTED(2)	
27. Suvai	☐	☐	_____
28. Ooru	☐	☐	_____
	☐	☐	

29. Oli
30. Oosai
31. Naatram

KANMENDHIRIYAM	NORMAL (1)	AFFECTED(2)	
32. Kai			
33. Kaal			
34. Vaai			
35. Eruvaai			
36. Karuvaai			

UYIR THATHUKKAL

VALI - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

37. Uyirkkal (Pranan)
    - Digestion
38. Keezhnokkukkal (Abanan)
    - Excretion of Urine
    - Excretion of Faeces
39. Paravukal (Viyanan)
    - Blinking
    - Movement of limbs
40. Melnokkukkal (Uthanan)
    - Eloquence
    - Complexion
    - Hiccup

41. Nadukkal (Samanan)

Digestion ☐ _____

42. Nagan

Hearing ☐ _____

Thinking ☐ _____

Closing &opening of eyelids ☐ _____

43. Koorman

Winking of eyelids ☐ _____

Yawning ☐ _____

Closing of mouth ☐ _____

44. Kirukaran

Salivary secretions ☐ _____

Hunger ☐ _____

45. Devathathan

Occular movements ☐ _____

Laziness ☐ _____

AZHAL - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

47. Aakkanal (Anar pitham)

Digestion ☐ _____

48. Vannayeri(Ranjagam)

Pallor ☐ _____

49. Aattralangi(Sathagam)

Movements ☐ _____

50. Olloli Thee (Prasegam)

Complexion ☐ _____

☐

Colour of Skin _____

Brightness of Skin ☐ _____

51. Nokkazhal(Alosagam)

Vision ☐ _____

IYAM - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

52. Aliiyam (Avalambagam)

Respiration ☐ _____

53. Neerppiyam(Kilethagam)

Digestion ☐ _____

54. Suvaikanaiyam (Pothagam)

Taste ☐ _____

55. Niraivaiyam (Tharpagam)

Cooling of eyes ☐ _____

56. Onriyaiyam (Santhigam)

Movements of joints ☐ _____

VATHAM ☐ PITHAM ☐ KABAM ☐ _____

UDAL THATHUKKAL	**INCREASED(1)**	**DECREASED(2)**
57. Saaram	◯	
Indigestion	☐	
Loss of Weight		☐
Tiredness		☐
Lassitude		☐
Dryness of the Skin		☐

Diminished activity of sense organs ☐

58. Senneer ◯

Boils ☐

Throbbing pain ☐

Anorexia ☐

Mental disturbance ☐

Splenomegaly ☐

Colic pain ☐

Increased BP ☐

Reddish Eye & Skin ☐

Jaundice ☐

Haematuria ☐

Anaemia ☐

Tiredness ☐

Lassitude ☐

Neuritis ☐

Pallor of body ☐

59. Oon ◯

Cervical Lymphadenitis ☐

Ulcers & Tumors ☐

Hypermuscular in cervical Region ☐

Impairment of sense organs ☐

60. Kozhuppu ◯

Dyspnoea ☐

Loss of Activity ☐

Pain in Hip

61. Enbu ○

Splitting & falling of hair ☐

Loosening of teeth & nail ☐

62. Moolai ○

Non- healing ulcer ☐

Swollen phalanges ☐

Swollen eyes ☐

Oliguria ☐

Heaviness of body ☐

Weakness of bone ☐

Sunken eyes ☐

63.Sukkilam/suronitham ○

Love & lust towards women/men ☐

Urinary calculi ☐

Failure of reproduction ☐

Pain in genitalia ☐

ENVAGAI THERVUGAL

NAA

64. Maa padithal Present ☐ Absent ☐

65. Niram Black ☐ Red ☐ Pale ☐ Others ☐

66. Suvai Inippu ☐ Pulippu ☐ Kaippu ☐ Thuvarppu ☐ Uvarppu ☐ Karppu ☐

67. Vedippu Present ☐ Absent ☐

68. Vai neerural Normal ☐ Excess ☐ Scanty ☐ Absent ☐

69. NIRAM (SKIN)

Karuppu ☐ Manjal ☐ Veluppu ☐ Maa niram ☐

70. MOZHI

Sama oli ☐ Uratha oli ☐ Thazhntha oli ☐

71. VIZHI

.Niram Black ☐ Red ☐ Yellow ☐ Pale ☐

72. Kanneer Normal ☐ Abnormal ☐

73. Yeritchal Present ☐ Absent ☐

74. Peelai Present ☐ Absent ☐

MEI

75. Veppam Mitha Veppam ☐ Miku Veppam ☐ Thatpam ☐

76. Viyarvai Normal ☐ Increased ☐ Reduced ☐

77. Thoduvali (Tenderness) Present ☐ Absent ☐

78. Vali (Pain) Present ☐ Absent ☐

79. NAADI

Vatham ☐ Pitham ☐ Kabam ☐ Vathapitham ☐ Vathakabam ☐

Pitha Kabam ☐ Pithavatham ☐ Kabavatham ☐ Kabapitham ☐

MALAM NORMAL (1) AFFECTED (2)

80. Niram Black ☐ Red ☐ Yellow ☐ Pale ☐

81. Thanmai (Consistency) Irukal ☐ Ilakal ☐ Thin ☐ Bulky ☐

82. Alavu Normal ☐ Increased ☐ Reduced ☐

83. Kazhichal Present ☐ ☐ Absent ☐ ☐

84. Seetham _____

85. Vemmai ☐ ☐ _____

MOOTHIRAM

NEERKURI NORMAL (1) AFFECTED (2)

86. Niram Venmai ☐ Manjal ☐ Sivappu ☐ Others ☐ _____

87. Nurai Normal ☐ Increased ☐ Reduced ☐ _____

88. Edai Normal ☐ Increased ☐ Reduced ☐ _____

89. Enjal (Alavu) Normal ☐ Increased ☐ Reduced ☐ _____

90. Manam Present ☐ Absent ☐ _____

91. Thadavai (Frequency) DAY ☐ NIGHT ☐ _____

NEIKKURI

92. Aravam ☐ 93.Mothiram ☐ 94.Muthu ☐

95.MANIKKADAI NOOL - VIRARKADAI

11	10	9 ¾	9 ½	9 ¼	9	8 ¾	8 ½	8 ¼	8
7 ¾	7 ½	7 ¼	7	6 ¾	6 ½	6 ¼	6		
5 ¾	5 ½	5 ¼	5	4 ¾	4 ½	4 ¼	4		

Date: Signature of Investigator/ Medical Officer

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA
OPEN LABELED CLINICAL TRIAL OF APNC IN PEENISAM (SINUSITIS)
Case Record Proforma - Laboratory Investigations – Before/After Treatment

BLOOD

i. TC: _____ cells/mm.

ii. DC : P___ % L___ % B___ % M___ % E___ %

iii. ESR: _____ mm ½ hour _____ mm 1 hour

iv. Hb : _____ gms% Absolute Eosinophil count ___ cells/mcL

v. Blood Sugar:

a. Fasting/ Random _____ mgms%

vi. Blood Urea : _____ mgms%

vii. Serum Creatinine : _____ mgms%

viii. Lipid Profile

a. Total Cholesterol : _____ mgms%

b. TGL : _____ mgms%

c. HDL: _____ mgms%

d. LDL: _____ mgms%

Bleeding time _____ min Sec

Clotting time _____ min Sec

VDRL: Positive ☐ Negative ☐

IgE _____ IU/ml

X- RAY: Para Nasal Sinuses:

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

OPEN LABELED CLINICAL TRIAL OF APNC IN PEENISAM (SINUSITIS)

CASE RECORD FORM III – Assessment Proforma

1. Code No (of clinical trial) | **043** |

2. Center **Siddha Central Research Institute, Chennai – 600 106**

3. Serial no of the subject | | | | |

3. Name of the subject Mr/Ms/Mrs. ----------

1st visit – 0th day

VITAL SIGNS

12. Pulse rate/min | | |

13. Heart rate/min | | |

14. BP(mmof Hg) | | | | / | | | |

15. Temperature ºF | | | . | |

	PRESENT (1)	ABSENT (2)
16. Cyanosis		
17. Anaemia		
18. Jaundice		
19. Clubbing		
20. Lymphadenopathy		
21. Oedema		

22. Height/cm | | | | . | |

23. Weight/Kgs | | | | . | |

24. BMI | | |

UYIR THATHUKKAL

VALI - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

37. Uyirkkal (Pranan)

Digestion ☐ _____

38. Kizhnokkukkal (Abanan)

Excretion of Urine ☐ _____

Excretion of Faeces ☐ _____

39. Paruvukal (Viyanan)

Blinking ☐ _____

Movement of limbs ☐ _____

40. Melnokkukal (Uthanan)

Eloquence ☐ _____

Complexion ☐ _____

Hiccup ☐ _____

41. Nadukkal (Samanan)

Digestion ☐ _____

42. Nagan

Hearing ☐ _____

Thinking ☐ _____

Closing &opening of eyelids ☐ _____

43. Koorman

Winking of eyelids ☐ _____

Yawning ☐ _____

Closing of mouth ☐ _____

44. Kirukaran

Salivary Secretions ☐ _____

Hunger ☐ _____

45. Devathathan

Occular Movements ☐ _____

Laziness ☐ _____

AZHAL - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

47. Aakkanal (Anar pitham)

Digestion ☐ _____

48. Vannayeri(Ranjagam)

Pallor ☐ _____

49. Aattralangi(Sathagam)

Movements ☐ _____

50. Olloli Thee (Alosagam)

Complexion ☐ _____

Colour of Skin ☐ _____

Brightness of Skin ☐ _____

51. Nokkazhal(Prasagam)

Vision ☐ _____

IYAM - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

52. Aliiyam (Avalambagam)

Respiration ☐ _____

53. Neerppiyam (Kilethagam)

Digestion ☐ _____

54. Suvaikanaiyam (Pothagam)

Taste ☐ _____

55. Niraivaiyam (Tharpagam)

☐

Cooling of Sense organs _____

56. Onriyaiyam (Santhigam)

Movements of joints ☐ _____

VATHAM ☐ PITHAM ☐ KABAM ☐ _____

UDAL THATHUKKAL	INCREASED(1)	DECREASED(2)
57. Saaram	◯	
Indigestion	☐	
Loss of Weight		☐
Tiredness		☐
Lassitude		☐
Dryness of the Skin		☐
Diminished activity of Sense organs		☐
58. Senneer	◯	
Boils	☐	
Throbbing pain	☐	
Anoerxia	☐	
Mental Disturbance	☐	
Splenomegaly	☐	
Colic pain	☐	
Increased BP	☐	
Reddish Eye & Skin	☐	
Jaundice	☐	
Hameturia	☐	
Anaemia		☐
		☐

Tiredness

Lassitude ☐

Neuritis ☐

Pallor of body ☐

59. Oon ○

Cervical Lymph adenitis ☐

Ulcers & Tumor ☐

Hypermuscular in cervical Region ☐

Impairment of Sense organs ☐

60. Kozhuppu ○

Dyspnoea ☐

Loss of Activity ☐

Pain in Hip ☐

61. Enbu ○

Splitting & Falling of Hair ☐

Loosening of Teeth & Nail ☐

62. Moolai ○

Non Healing ulcer ☐

Swollen Phalanges ☐

Swollen eyes ☐

Oliguria ☐

Heaviness of body ☐

Weakness of bone ☐

Sunken eyes

63.Sukilam/suronitham ◯

Love & Lust towards women/men ☐

Urinary calculi ☐

Failure in reproduction ☐

Pain in genitalia ☐

Severity of symptoms at baseline and subsequent follow ups

Symptoms	**Base line**	**Follow up (weeks)**						**Remarks**
		1	**2**	**3**	**4**	**5**	**6**	
Irritation & Burning Sensation								
Watery Discharge								
Redness & lacrimation of the eyes								
Nasal Speech								
Itching & blockage of ears								
Heaviness of the Head								
Difficulty in breathing								
Head Ache								
Nasal congestion								
Dull Ache In Mid Face								
Sneezing								
Giddiness								
Rhinorrhea								

Symptoms		**Base line**	**Follow up(Weeks)**						**Remarks**
			1	**2**	**3**	**4**	**5**	**6**	
Vatham									
Viscous Mucous Discharge									
Fetid smell									
Head ache									
No block									
Dryness in the Nose									
Tenesmus in scalp									

Symptoms		**Base line**	**Follow up(Weeks)**						**Remarks**
			1	**2**	**3**	**4**	**5**	**6**	
Pitham									
Yellowish Discharge									
Smell of Flush									
Occ. Head ache									
Both Nasal block									
Angry look with redness									
Symptoms		**Base line**	**Follow up(Weeks)**						**Remarks**
			1	**2**	**3**	**4**	**5**	**6**	
Kabam									
Thick heavy congeals of mass of phlegm									

Offensive smell of decomposing body									
Pricking pain in head									
Alternate Nasal Block									
Increased Sneezing									
Gummy secretion of the eyes									

Absent = 0 Mild=1 Moderate=2 Severe=3

Integrated Medicine Outcomes Scale' (IMOS)

(A five point verbal rating scale)

1. **COMPLETE RECOVERY** ○
2. **MAJOR IMPROVEMENT** ○
3. **SLIGHT TO MODERATE IMPROVEMENT** ○
4. **NO CHANGE** ○
5. **DETERIORATION** ○

Subject Signature

Date:

Signature of Investigator/ Medical Officer

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

OPEN LABELED CLINICAL TRIAL OF APNC IN PEENISAM (SINUSITIS)

DRUG COMPLIANCE REPORT FORM – I

(To be filled by the trial participant)

(To be issued on 1st visit - 0 day and taken back on 2nd visit -15th day)

Registration No. of participant _____

Name of the participant _____

Please come for next visit on .....(Date and time is to be filled by the Investigator)

Instructions to trial participant

- Please take Capsule (APNC) twice a day after food.
- Please return the unused capsule along with the Drug Compliance Form duly filled.

S.no	Date	**Morning Dose (Around 9 AM)**		Evening dose (Around 8 PM)	
		Please put mark after taking the Medicine	**Please enter the time**	**Please put mark after taking the Medicine**	**Please enter the time**
1.					
2.					
3.					
4.					
5.					
6.					

S.no	Date	**Morning Dose (Around 9 AM)**		Evening dose (Around 8 PM)	
		Please put mark after taking the Medicine	**Please enter the time**	**Please put mark after taking the Medicine**	**Please enter the time**
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					

Name of the Participant: _____

Date: _____

Signature or Thumb impression of the participant

Signature of the Investigator with date