

Central Council for Research in Siddha

SINGLE BLIND CLINICAL TRIAL OF FORMULATIONS IN THE TREATMENT OF ERAIPPUNOI (BRONCHIAL ASTHMA)

PROTOCOL

1. Introduction

Bronchial Asthma is defined as paroxysms of dyspnoea accompanied by wheezing, resulting from temporary narrowing of the bronchi by muscle spasm, mucosal swelling or viscid secretion.

In Siddha system of medicine also this clinical entity has been recognized as Eraippu Noi with elaborate description on various aspects like causative factors, signs and symptoms and management. Though currently available modern medicines can effectively control, the side effects produced by them are many. Screening of herbal and herbo-mineral medicines in the treatment of Eraippu noi may be useful for the drug development authority.

2. Aim

To evaluate the therapeutic efficacy of BA1, a coded drug in the management of bronchial asthma.

3. Trial design

Double blind clinical trials.

4. Sample size

30 cases

5. Duration of treatment

45 days

6. Criteria for selection

16 – 50 years of both sexes

7. Clinical parameters

Dyspnoea

Tightness of chest

Wheezing

Duration: Upto 5 years of duration history.

8. Criteria for exclusion

Age below 16 years and above 50 years

Duration of illness for more than 5 years

Cardiac asthma

Renal asthma

Tuberculosis

Carcinoma of lungs

Lung abscess

Bronchiectasis.

9. Criteria for withdrawal

If the disease could not be managed with this drug and the condition wherein ventilation nebulizer and steroid are warranted to provide relief.

10. Methods of Assessment

Every week the cardinal signs and symptoms will be monitored and the pulmonary function tests will be done on the 1st and subsequent weeks upto 6th week, and will be monitored. On the completion of 6th week the pulmonary function tests will be carried out and the changes will be statistically analyzed. Clinical investigations like TC, DC, ESR, Hb% sugar, urea will also be carried out and assessed at the starting and after the completion of the clinical trial.

11. Period of study

The study will be completed within a year or as long as required samples are available.

12. Statistical analysis

Suitable method of Statistics will be applied to analyze the data collected to find out the statistical significance.

13. Ethical Review

Clearance certificate from institutional ethical committee or Head of the institute will be obtained before starting the clinical trial patient's consent form and information form will be issued to all patients and their consent will be obtained.

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**SINGLE BLIND CLINICAL TRIAL OF FORMULATIONS IN THE
TREATMENT OF ERAIPPUNOI (BRONCHIAL ASTHMA)**

PATIENT INFORMATION SHEET

WHAT IS THE STUDY ABOUT?

Bronchial asthma is defined as paroxysms of dyspnoea accompanied by wheezing, resulting from temporary narrowing of the bronchi by muscle spasm mucosal swelling or viscid secretion.

In Siddha system of medicine also this clinical entity has been recognized as Eraippu noi - (Kuppusamy Mudaliar.K.V. 1954) with elaborate description on various aspects like causative factors, signs and symptoms and management. Though currently available modern medicines can effectively control, the side effects are many. Screening of herbal and herbomineral medicines can be very useful for an effective drug development strategy. So, with an aim to cull out an effective herbal therapy it is planned to formulate a formula containing xxx on Bronchial Asthma .

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 45 days to complete. During the period you are expected to visit the hospital once in a week for treatment.

Before you start the treatment, during the first visit to the clinic, you will undergo a complete physical examination and PFT (Pulmonary Function Test).

If you were found eligible, you would be put on trial treatment for 45 days. The daily dosage will be 500 mg twice a day. At each visit, you will be supplied with sufficient quantities of drugs to last until your next visit. On completion of the treatment PFT will be done again to assess the effect of the treatment. Bio-chemical investigations will also be carried out once in every two weeks.

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Single blind clinical trial of Siddha formulations in the treatment of Bronchial Asthma.

Form I –screening Proforma

1. Name of the Person : _____
2. Gender : _____
3. Date of Birth : _____
4. Age : _____
5. Address : _____

Criteria for inclusion

6. Dyspnoea :
7. Tightness of the chest :
8. Wheezing :

Criteria for exclusion

9. Age below 16 years and above 50 years :
10. Duration of illness for more than 5 years :
11. Cardiac Asthma(Left ventricular failure) :
12. Renal Asthma :
13. Tuberculosis :
14. Carcinoma of lungs :
15. Lung abscess :
16. Bronchiectasis :

Date:

Signature of Doctor.

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**SINGLE BLIND CLINICAL TRIAL OF SIDDHA FORMULATIONS IN THE
TREATMENT OF BRONCHIAL ASTHMA.**

FORM II –HISTORY PROFORMA

1. Sl.No of subject
2. Name of the Person
3. Gender
4. Date of Birth
5. Age
6. Educational status
Literate Read and Write
Educational qualifications
7. Past occupation
Desk Work Field work -physical labour Field work / intellectual
Indicate the nature of Work
8. Occupation
Desk Work Field work - physical labour Field work / intellectual
Indicate the nature of Work
9. History of Attacks
10. Duration of Illness
11. Attacks /Typical
12. Onset/ gradual/acute
13. Attacks
14. Seasonal
15. Fever
16. History of Allergy
17. Bedroom dusting
18. Food stuffs Eggs/Milk/Potato/Fish/Prawn/Other foods ; Attacks during
rainy season
19. Drug allergy
20. Home surrounding
21. Mat/ Bed sheet with cotton pillow
22. Cotton mattress and pillow
23. Foam mattress
24. Pets -Dogs /Cats /Cattle Sheep
25. Special exposure pollen
26. Menstrual History
27. History of Respiratory infection
28. Cold
29. Head ache
30. Sneezing
31. Rhinorrhoea

32. Surgical intervention

Antral puncture

Deviated septum Correction

Tonsillectomy

33. Personal history

34. Occupation

35. Economic status

36. Social status

37. Number in the family

38. Position in the family

39. Death in the family

40. Psychological factors

41. History of Associated conditions

Eczema

Urticaria

Migraine

Allergic rhinitis

Allergic head ache

Allergic dermatitis

Contact dermatitis

42. Family history

Any member of the family having any allergic disorder or having had any one of them during their life time

Father

Mother

Grand parents

Other relations

43. Past history

Has the patient suffered from any disease or condition in the past which required hospitalization or prolonged treatment?

Medical

Surgical

Gynecological

Obstetrical

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FORM II – CLINICAL ASSESSMENTS

1. Serial No. of the Subject :
2. Name :
3. Gender : Male Female
4. Date of birth : Age years
5. Date of assessment :
Month of assessment: Initial
- | | |
|----------------------|----------------------|
| 1 st week | 2 nd week |
| 3 rd week | 4 th week |
| 5 th week | 6 th week |

SIGNS AND SYMPTOMS OBSERVED:

1. Sneezing :
2. Cough :
3. Wheezing :
4. Gaspings :
5. Dyspnea :
6. Sputum with cough :
7. Husk 'c' voice :
8. Hydrosis :
9. Running nose :
10. Sore throat:
11. Pain in chest :
12. Expectoration :

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FORM III – LABORATORY INVESTIGATIONS

1. Serial No. of the Subject :
2. Name :
3. Gender : Male Female
4. Date of birth : Age
5. Date of assessment :
Month of Assessment : Initial 1st week
2nd week 3rd week
4th week 5th week
6th week

Investigations:

- Urine : Blood:
Motion : TC
Sputum : DC
X-Ray Chest : ESR
Hb %
Sugar:
Urea:

Endermal Test:

Management:
(With indigenous drug)

Pulmonary Function Tests: