IJPSR (2025), Volume 16, Issue 1 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 01 August 2024; received in revised form, 01 September 2024; accepted, 25 October 2024; published 01 January 2025

A SINGLE-CENTRIC, SINGLE-ARM PILOT STUDY TO EVALUATE THE SAFETY AND EFFECTIVENESS OF *SWASA KUDORI CHOORANAM (*SKC) IN THE MANAGEMENT OF *SWASA KAASAM* (BRONCHIAL ASTHMA) - A STUDY PROTOCOL

Shunmugaram Shenbagaraj *, Vinodini Ramamoorthy, Lavanya Alagusolaiyan, Saraswathi Balasubramanian and Sathiya Rajeswaran Parameswaran

Siddha Regional Research Institute, Kuyavarpalayam - 605013, Puducherry, India.

Keywords:

Siddha medicine, *SwasaKaasam*, *Swasa Kudori Chooranam*, Bronchial asthma, modified Medical Research Council Dyspnoea Scale, Asthma Control Test, Asthma Quality of Life Questionnaire

Correspondence to Author:
Dr. S. Shunmugaram M.D (Siddha)

Research Officer (Siddha),
Siddha Regional Research Institute,
Kuyavarpalayam - 605013,
Puducherry, India.

E-mail: dr.s.s.ram28@gmail.com

ABSTRACT: Background: *Cuvācakācam (SwasaKaasam)* is one of the twelve types of *Kācam* in Siddha System of Medicine and is clinically correlated with Bronchial Asthma. Asthma is a Non-Communicable Disease that affects global health invariably by affecting all age groups with 5th global rank in terms of Daly's. According to GBD, 13.09% of the population in India suffered from asthma and the prevalence in Puducherry was 8.6%. The present conventional anti-asthmatic drugs have several side effects, and the patient's QoL is also compromised. Thus, it is imperative to explore alternative or complementary therapeutic techniques in view of adverse effects, out-of-pocket expenses, and patient compliance. **Aim:** The present study aims to evaluate the safety and effectiveness of *Swasa Kudori Chooranam* in Bronchial Asthma patients. **Methods:** This is a single-arm pilot study of 37 participants with a known history of *Cuvācakācam* (Bronchial asthma). Trial drug will be advocated for a period of 30 days as per the prescribed dose followed by baseline investigations. The outcome assessments included PFT, ACT, mMRC Dyspnoea Scale, AQLQ(S); safety parameters such as LFT, RFT, CRP, AEC and Urine routine will be done on D0, D15, D30 and D121. The Reduction in frequency of allopathic drug usage throughout the study period will also be assessed. **Discussion:** This trial is an attempt to explore the safety and effectiveness of SKC for bronchial asthma disease management and quality of life. **Trial Registration:** The trial was prospectively registered in the Clinical Trial Registry of India (CTRI) - CTRI/2024/03/064944.

BACKGROUND: *Cuvācakācam* (ISMT 4.9.6 – *Swasa Kaasam*) described as one of the twelve types of *Kācam* in the Siddha System of Medicine and is clinically correlated with bronchial asthma (J45). *Cuvācakācam* is characterized by paroxysmal dyspnoea associated with discomfort in the chest.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.16(1).167-74

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(1).167-74

The Siddha text *Yūki vaittiya cintāmaṇi* describes the symptoms of *Cuvācakācam*, which include a severe cough with or without expectoration, breathing sounds like a snake hissing, frequent humming, a sense of heat in the nostrils, emaciation, hoarseness in speech, indigestion, flatulence, and excessive mucous secretion [1].

Asthma is a noncommunicable disease that affects the global health invariably by affecting all age groups. It is a heterogeneous chronic airway inflammatory disease characterized by recurrent attacks of cold, cough with expectoration of tenacious mucoid sputum, wheezing, chest tightness and shortness of breath. Hereditary,

allergic conditions such as eczema, urbanization, lifestyle changes, smoking, emotional stress, and exposure to chemicals, fumes, dust, molds and house dust mites are such factors that trigger asthma. Children and adults who are overweight or obese are at greater risk of asthma. Asthma is often under diagnosed or undertreated in low- or middle-income countries. Due to disrupted sleep patterns, daytime fatigue and difficulty in concentration, asthma impacts people's employment, education, physical activity, emotional well-being, social and personal relationships [2].

According to WHO report, asthma affected 262 million people worldwide and accounted for 4,55,000 deaths in 2019. As per the Global Burden of Disease (GBD, 1990 - 2019), approximately 34.3 million individuals in India Suffering with asthma, which represents 13.09% of the global burden [3] and the prevalence in the Puducherry Union territory was 8.6% [4].

It is a chronic disease and ranks 5th globally in terms of Disability-Adjusted Life Years (DALYs). Furthermore, asthma accounts for 27.9% of DALYs among the population of India and causes 13.2 deaths per thousand people [3]. The incidence of BA (*Cuvācakācam*) in the Outpatient Department of the Siddha Regional Research Institute, Puducherry is around 5%. The therapeutic management of BA focuson preventing chronic BA symptoms that interfere with day-to-day activities and enhancing quality of life. Due to complex pathophysiology of the disease the treatment options will vary depends upon the disease severity and associated symptoms. Current conventional anti-asthmatic drugs that are widely prescribed have several side effects including nausea, headaches, and convulsions (xanthine class; cardiovascular effects (β-adrenergic receptor antagonists); vomiting (PDE4 inhibitors drugs); osteoporosis, myopathies, adrenal suppression, and metabolic disturbances, compromising children's growth (corticosteroids). Patient quality of life is jeopardized by these side effects, which also significantly decreases compliance [5]. *Derakhshan et al.;* revealed that long-term use of herbal medicines for asthma treatment, significantly improved the lung functions without any side effects compared to standard allopathy management [6]. Furthermore, an individual suffering from asthma fails an average of 17 days of work per year and incurs direct expenses ranging from ₹13,010 to ₹23,918 annually [7]. Thus, it is imperative to explore alternative therapeutic techniques or complementary therapies in view of adverse effects, out-of-pocket expenses, and patient compliance with present medications. There has been a paradigm shift towards traditional Siddha management for various ailments since Covid 19 will evident the role of Siddha medicine in pandemics. *Swasa Kudori Chooranam* (SKC) is expounded by Saint *Akattiyar* in *Akattiyar vaittiya kāviyam*- 1500 and is also authorized as a sastric preparation by the Drugs and Cosmetic Act, Government of India. SKC indicated for 96 types of respiratory disorders, cold, cough and tuberculosis [8]. *In-vitro* studies of SKC revealed that it exhibited potent bronchodilator activity at a dose of 200 mg/kg by lowering the leukocyte count and milk-induced eosinophilic count [9].

The acute and chronic anti-inflammatory activity of SKC exhibited by H. Vetha. *et. al* at a dose of 100 mg/ml used the Hind Paw and Cotton Pellet Granuloma methods, while 20 mg/ml ibuprofen was used as a standard [10]. Acute and subacute toxicity studies of the drug SKC revealed that there were no fatalities or abnormalities in the haematological or biochemical profile; thus, the drug is safe for long-term human administration [11]. However, no specific clinical trial has been conducted yet; this trial aimed to evaluate the safety and effectiveness of SKC in mild to moderate BA. This Study protocol was prepared in accordance with SPIRIT guidelines.

MATERIALS AND METHODS:

Aim and Objectives: The present study aims to evaluate the safety and effectiveness of *Swasa Kudori Chooranam* in BA patients.

Primary Objective: To evaluate the effectiveness of the trial drug by:

1. Mean change in Forced Expiratory Volume in one second (FEV1) and Forced Vital Capacity (FVC) on the 16th day, 31st day and 121st day from baseline.
2. Mean change in the Asthma Control Test (ACT) [12] and modified Medical Research

Council (mMRC) Dyspnoea Scale [13] score on 16th day, 31st day and 121st day from baseline.

3. Mean change in the Asthma Quality of Life Questionnaire with Standardized Activities [AQLQ(S)] [14] on 16th day, 31st day and 121st day from baseline.

Secondary Objective:

a. To evaluate the safety of the trial drug *Swasa Kudori Chooranam* at a dose of 1 gm.

b. To evaluate the reduction in frequency of allopathic drug usage throughout the study period.

Study Design:
Methods:

- Intervention model: Single arm open prospective trial.
- Assessment tools:
  - Clinical improvement - Physical examination, ACT, mMRC Dyspnoea Scale
  - Effectiveness of the trial drug - Pulmonary Function Test (FEV1 & FVC).
  - Safety of the trial drug - LFT, RFT, CRP and Urine routine
  - QoL of the Trial participants - AQLQ(S).
- Study duration: 2 years.

Study Site: Patients visiting the Outpatient department of Siddha Regional Research Institute (SRRI), Puducherry, will be screened for eligibility and recruited.

Sample Size: Since, there are no similar studies in practice, this trial aimed to conduct a pilot study to measure the effectiveness of SKC. To meet the normality assumption, at least 30 samples were needed; hence, we fixed the sample size at 37 with an expected drop out of 20% (7 cases) during the study (37 – 7 = 30 samples).

Eligibility Criteria:
Inclusion Criteria: The patient must fulfil the following criteria for taking part in the study:

- Age 18 - 60 years - either gender
- Symptoms of dry cough, recurrent attacks of dyspnoea, hoarseness of voice, chest tightness, profuse sweating, and wheezing
- Asthmatic attack due to seasonal changes and allergens
- Those who are willing to take radiological investigation and provide blood samples for laboratory investigation.
- FEV1 with 50-80%

Exclusion Criteria: Patients who met the following criteria will not be eligible to participate in the study:

- Asthma associated with COPD.
- Unstable bronchial asthma or status asthmaticus.
- Asthma exacerbation during the past month.
- COVID 19 positive patients (at the time of recruitment)
- Tuberculosis, pneumonia, and bronchogenic carcinoma
- Cardiac, Liver and Renal diseases.
- Participation in another clinical trial within the preceding 90 days of the study started.
- Pregnant and lactating women.
- Participants with a continuing history of alcohol, smoking or drug abuse.

Who will Obtain Informed Consent: The Principal Investigator (PI)/ Co-Investigator (Co-I)/ Research Associate (RA) will elaborate about the clinical trial to the participants and will obtain informed consent.

Recruitment: People who visit the SRRI, Puducherry, Clinical section OPD, with known the complaints of BA will be referred to the RA for further trial recruitment by physician. If the participant agrees for screening process, the PI or RA will elaborate about the clinical trial and advised to read the bilingual patient information sheet. The patient will be given adequate time to read and go through the information sheet and if they have any additional queries, it will be clarified. If the participant is interested and willing to consent immediately, the PI / RA will review the informed consent process to the participant and obtain the signatures required for enrollment in the

study. In cases of illiteracy, the participants are requested to provide the consent with the help of an attender. While screening physical examinations, laboratory investigations such as CBC, Diabetic profile, RFT, LFT, urine routine, CRP, AEC, Sputum AFB, PFT and Radiological investigations will be done to the participants. If the participants fulfil the inclusion criteria, they will be recruited and allocated unique ID, and an individual case file will be maintained. The excluded participants will be advised to consult the Clinical Section of the SRRI, Puducherry. The complete recruitment processes as well as the intervention and follow-up periods are elaborated in **Table 1** and **Fig. 1.**

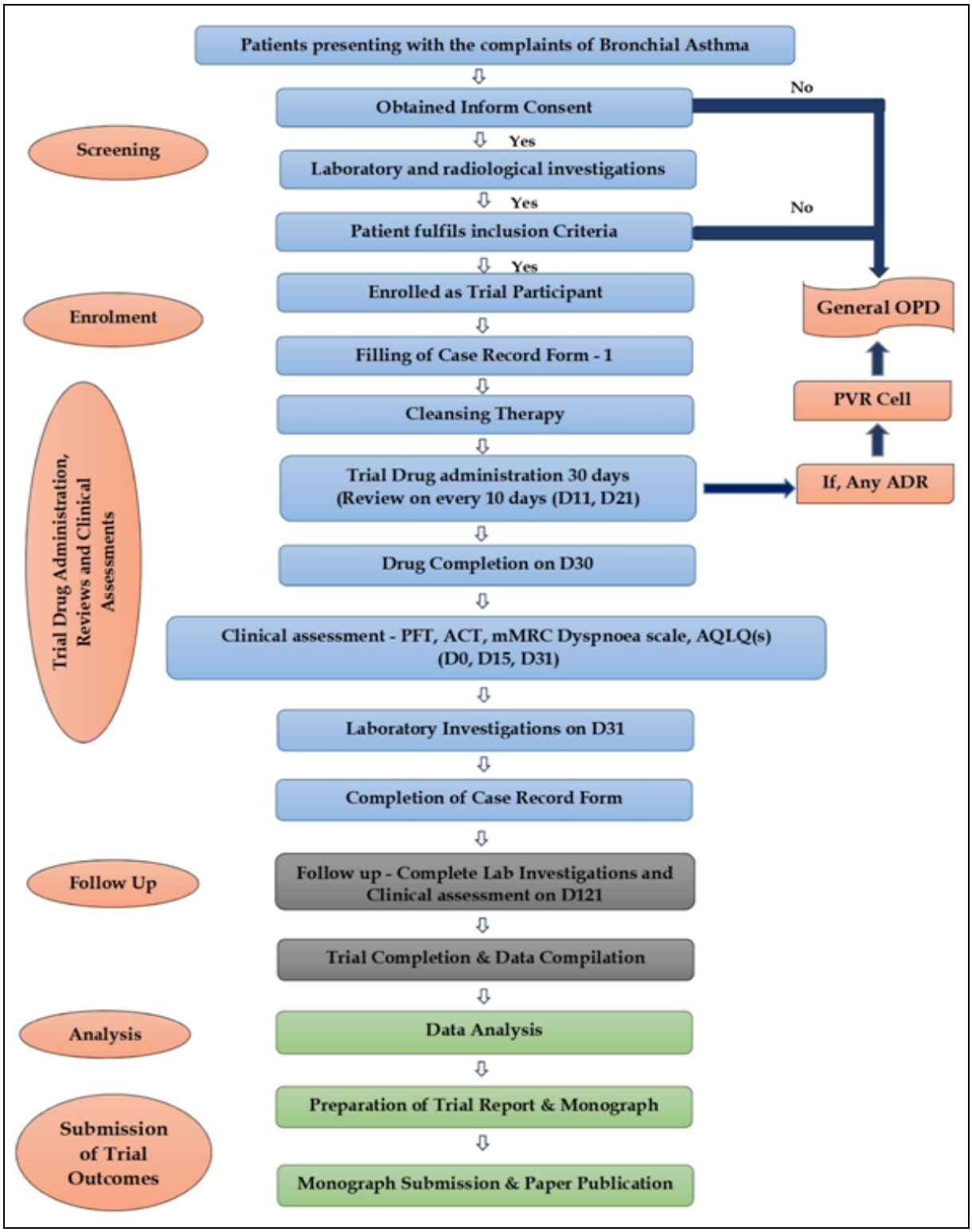

FIG. 1: FLOWCHART OF THE CLINICAL TRIAL

TABLE 1: STUDY VISIT AND ASSESSMENT TIMELINE

Time point	Study period						
	Enrollment/Screening	Trial period					Follow-up period
		D0	D1	D11	D15	D21	D31	D121
Enrollment								
Eligibilityscreen	x							
Informed consent	x							
Intervention								
Purgation therapy		x						
Swasa KudoriChooranam			x	x	x	x		
Assessments								
Physical Examination	x	x	x	x	x	x	x	x
Clinical assessment								
AsthmaControlTest(ACT)		x			x		x	x
mMRCDyspnoeascale		x			x		x	x
AQLQ(S)		x			x		x	x
Laboratory assessment								
Laboratory investigations(Blood& Urine)	x						x	x
Pulmonary FunctionTest	x				x		x	x
SputumAFB	x							
X- Ray Chest– PAview	x							
Siddha diagnostic assessment								
Nāṭi		x	x	x	x	x	x	x
Neykkuṟi		x					x	x
Tēka ilakkaṇam		x					x	x
Maṇikkaṭai nūl		x					x	x

Intervention:

Cleansing Therapy: The participants will be advised to take purgation medicine before Ingestion of the trial drug. *Akattiyar kuḻampu* will be given internally at a dose of 130 mg with ginger juice on day 0 for purgation. During purgation, participants have been advised to follow dietary restrictions, do's and don'ts mentioned in the drug compliance form.

Trial Drug Description:

Study Drug: *Swasa Kudori Chooranam* (SKC): The trial drug was procured from Indian Medical Practitioners Co-operative Pharmacy and Stores ltd., in a 30-gm package with proper labelling.

Ingredients of SKC: *Cukku* (*Zingiber officinale*), *Miḷaku* (*Piper nigrum*), *Tippili* (*Piper longum*), *Ciṟṟarattai* (*Alpinia officinarum*), *Akkarakāram* (*Anacyclus pyrethrum*), *Vālmiḷaku* (*Piper cubeba*), *Tippili kaṭṭai*(*Piper longum*), Purified *Veṅkāram* (Sodium Biborate – Borax), *Tāḷicapattiri* (*Abies spectabilis*).

Dosage: 1 gm of SKC with honey, Three times in a day (TDS).

Duration of the Treatment: 30 days

Follow-up period: 3 months.

Drug Dispensing: Drug administration will be started followed by the cleansing therapy. Participants will receive a single pack of the trial drug and 100 ml of honey, along with a sample dose of 1 gm of trial drug in a butter sheet.

The participant will be advised to take the medicine as such at the sample dose and to visit the OPD once in every ten days. The clinical assessment will be performed at each visit, and the next dose of the trial drug will be dispensed.

They will advise to fill out the drug compliance form and submit it to the investigator, to ensure the adherence of the trial participants.

Withdrawal Criteria: 1. If the participant could not follow the necessary instructions or if any serious condition that requires immediate treatment, the participant may be withdrawn from the trial. 2. Patients who miss the drug regimen for five consecutive days will be treated as noncompliant, and the participant may be withdrawn from the study. 3. Increase in the severity of symptoms.

Plans for Adherence to Interventions: The participants will be educated about the study intervention and impact of the study outcome. Additionally, the PI, Co-I or RA will monitor the participants; and send phone reminders prior to each visit.

Concomitant Care in the Trial: Participants in the trial will be advised not to self-medicate for any condition and to contact the investigator if they experience any unusual symptoms.

To alleviate the emergency condition the participants will be permitted to use rescue medication as per the protocol and the same will be documented in the drug compliance form.

Post-trial Care: The trial participants who complain the symptoms of BA or any other ailments in the post-trial period will be treated with available OPD drugs in the SRRI, Puducherry.

Outcome Measurements:

Primary Outcome: 1. The effectiveness of the trial drug will be assessed by the mean change in PFT, ACT and mMRC Dyspnoea Scale from baseline. 2. The effectiveness of the trial drug will be assessed by the mean change in quality of life of trial participants assessed by AQLQ(S) from baseline.

Secondary Outcome: 1. Safety of the study drug will be assessed by using following parameters: LFT, RFT, CRP and Urine routine. 2. The effectiveness of the trial drug will be assessed by the mean change in the reduction in the usage of allopathic drugs for acute asthmatic attacks.

Data Collection, Management and Confidentiality: As per the protocol the participants will be allocated unique ID followed by Informed consent. The CRF, laboratory investigation and clinical assessment forms will be masked with a particular unique ID and stored securely in a lock system by the PI/Co-I/RA.

The records containing personal information will be stored separately; and the study records will be identified by unique ID numbers. Patient confidentiality will be maintained in the CRF, and the deidentified data will be used for publication and in the scientific forum. The investigator will keep all clinical study records for a minimum period of five years followed by the completion of the study.

Statistical Analysis: Data such as clinical assessments, laboratory parameters and any adverse reactions will be entered into the Excel sheet and analysis will be performed using IBM-SPSS software version 26.0, to compare the changes from baseline. The end points will be analysed descriptively as frequencies and percentages. Regression modelling analysis is used to assess the relationships between independent variables, dependent variables and vice versa. The disease trend and pattern in seasons (*kārkālam, kūtirkālam, etc*.,) will be analysed by longitudinal data analysis.

Data Monitoring Committee (DMC): This is an institutional based clinical trial, will be conducted in accordance with the protocol approved by the Institutional Human Ethical Committee (IHEC). The IHEC is the attorney to cross check the clinical data of the trial at any phase; to ensure that the study has been conducted as per the protocol without any violation or deviation. Therefore, this study does not require DMC.

ADR/ AE Reporting: At each visit the PI/ RA will enquire the trial participants whether they have experienced any unwanted reactions during the ingestion of the last course of medicine. If any adverse events / drug reactions occurs, that will be documented on the adverse drug reaction form of the CRF and will be reported to the IHEC and Pharmaco-Vigilance Cell of the institute not later than 10 calendar days. After documentation, the participant must be excluded from the trial and referred to either the Government hospital or the SRRI OPD for further management.

Protocol Amendments Communication: After the requisite modifications of the protocol were approved by the IHEC, the same will be submitted to the Scientific Advisory Board (SAB) for further approval.

Dissemination Plans: To reach the intended audience, the study's findings will be presented at international conferences, webinars, and published in peer-reviewed scientific journals. The PI will disseminate the deidentified data upon reasonable request.

DISCUSSION: Bronchial Asthma is a chronic inflammatory disease of the airways characterized by bronchial hyper reactivity and airway obstruction. In modern medicine, long-lasting effective management of symptoms which consists of anti-asthmatic drugs, patient awareness, and preventive measures, is the main goal of treatment for Asthma [15].

Therefore, *Swasa Kudori Chooranam* is hypothesised as a study drug, which aims to evaluate alternative traditional therapeutic management of bronchial asthma. The toxicity profile, bronchodilator activity, and anti-inflammatory activity of the trial drug revealed it as a more potent choice.

This protocol describes the methodology for a pilot study to determine the safety and effectiveness of SKC in human participants; we hope that this pilot study will pave the way for further studies. An RCT with a sizable sample size can be carried out if the study results are statistically significant.

Study Limitations: As this is a single-arm, nonrandomized pilot study and the study may be limited to this region, the effectiveness of the drug in other tropical climates will be explored further in phase II / phase III clinical trials. The exclusion criteria limit participants with severe asthma (FEV1 $\geq$ 80), diabetes mellitus, hypertension, vulnerable populations such as paediatric and geriatric population.

Trial Status: The trial prospectively registered in CTRI and the pretrial procedures are under process. Recruitment is about to commence. Anticipating recruitment will be commenced on November 2024 and the trial will be completed by December 2025.

Declaration:

Ethics Approval and Consent: The study protocol was approved by the Institutional Human Ethical Committee of the Siddha Regional Research Institute (Central Council for Research in Siddha), Puducherry [SRRI/2021-22/IHEC/EA-1(A)]. Informed consent will be obtained from all trial participants during enrolment.

Trial Registration: The trial prospectively registered in Clinical Trial Registry of India (CTRI/2024/03/064944).

Protocol Number and Version: SCT/SRRI/2021/02&Version 3.0/ Dated 15.12.2023

Availability of Data and Materials: Some restrictions are applied for data availability. Nonetheless, data from the author SSR are accessible upon justifiable request and with PS's consent.

Source(s) of Support: The present study is funded by the IMR Scheme of the Central Council for Research in Siddha (CCRS), Ministry of Ayush, Government of India.

Role of Sponsor: The sponsor is the monitoring authority that the trial has been conducted in accordance with the protocol AYUSH GCP. The sponsor will conduct a periodic review meeting regarding project's technical and financial aspects to ensure that Quality Assurance (QA) and Quality control (QC) are being met.

Author Contributions: Conceptualization - SSR Methodology - SSR Validation - PS Investigation - SSR, AL, RV Data Analysis - SSR, AL Writing - Original Draft - SSR, AL, RV, BS Manuscript Writing - Review & Editing - SSR, AL, RV, BS Visualization - SSR, PS Supervision - PS, Project administration – PS.

ACKNOWLEDGEMENTS: The authors gratefully acknowledge the guidance and support given by Prof. Dr. N. J. Muthukumar, Director General, Central Council for Research in Siddha, Chennai.

CONFLICTS OF INTEREST: The authors declare no conflicts of interest.

REFERENCES:

1. Mudaliar KNK: Siddha Maruthuvam Podhu (New Edition) vol. 1. Department of Indian Medicine and Homeopathy Publishers; Chennai 2012.
2. Asthma. (n.d.). Retrieved May 25, 2024, from https://www.who.int/news-room/fact-sheets/detail/asthma.
3. Singh S, Salvi S, Mangal DK, Singh M, Awasthi S, Mahesh PA, Kabra SK, Mohammed S, Sukumaran TU, Ghoshal AG, Barne M, Sinha S, Kochar SK, Singh N, Singh U, Patel KK, Sharma AK, Girase B, Chauhan A, Sit, N and Singh V: Prevalence, time trends and treatment practices of asthma in India: the Global Asthma Network study. ERJ Open Research 2022; 8(2): 00528-2021. https://doi.org/10.1183/23120541.00528-2021

4. Kumar GS, Roy G, Subitha L & Sahu SK: Prevalence of bronchial asthma and its associated factors among school children in urban Puducherry, India. Journal of natural Science Biology and Medicine 2014; 5(1): 59–62. https://doi.org/10.4103/0976-9668.127289
5. Azman S, Sekar M, Wahidin S, Ga SH, Vaijanathappa J, Bonam SR, Alvala M, Lum PT, Thakur V, Beladiya JV & Mehta AA: Embelin Alleviates Severe Airway Inflammation in OVA-LPS-Induced Rat Model of Allergic Asthma. Journal of Asthma and Allergy 2021; 14: 1511–1525. https://doi.org/10.2147/JAA.S298613
6. Derakhshan A, Sadeghi M, Asnaashari AM, Dehghani M, Salari R, Khadem-Rezaiyan M, Mirsadraee M, Saeidinejat, S, Jalali S & Jalali S: Efficacy of Herbal Medicines on Lung Function in Asthma: a systematic review and meta-analysis of randomized controlled trials. Journal of Pharmacopuncture 2023; 26(2): 124–138. https://doi.org/10.3831/KPI.2023.26.2.124
7. Aneeshkumar S & Singh RB: Economic burden of asthma among patients visiting a private hospital in South India. Lung India: official organ of Indian Chest Society 2018; 35(4): 312–315. https://doi.org/10.4103/lungindia.lungindia_474_17
8. Ministry of AYUSH, Government of India. The Siddha Formulary of India Part II. 1st edition 2011; 26-27.
9. Yadav RN, Kingsly A, Esakkypandian G and Duraichi AR: Bronchodilator activity of Swasa Kudori Chooranam. Int J Curr Res Chem Pharm Sci 2017; 4(9): 5-8. DOI: http://dx.doi.org/10.22192/ijcrcps.2017.04.09.002
10. Vetha H, Karthikeyan Karu & Nalini SH: Acute and chronic anti inflammatory study of a siddha medicine "swasakudori chooranam". International Journal of Pharmacy and Biological Sciences 2014; 4: 56-58.
11. Selvi TR: A Toxicity study on Swasa Kudori Chooranam. Doctoral dissertation, Government Siddha Medical College, Palayamkottai 2021.
12. van Dijk BCP, Svedsater H, Heddini A, Nelsen L, Balradj JS & Alleman C: Relationship between the Asthma Control Test (ACT) and other outcomes: a targeted literature review. BMC Pulmonary Medicine 2020; 20(1): 79. https://doi.org/10.1186/s12890-020-1090-5
13. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW & Wedzicha JA: Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. Thorax 1999; 54(7): 581–586.
14. Juniper EF, Buist AS, Cox FM, Ferrie PJ & King DR: Validation of a standardized version of the Asthma Quality of Life Questionnaire. Chest 1999; 115(5): 1265–1270. https://doi.org/10.1378/chest.115.5.1265
15. Ukena D, Fishman L & Niebling WB: Bronchial asthma: diagnosis and long-term treatment in adults. Deutsches Arzteblatt International 2008; 105(21): 385–394. https://doi.org/10.3238/arztebl.2008.0385

How to cite this article:
Shunmugaram S, Vinodini R, Lavanya A, Saraswathi B and Sathiyarajeswaran P: A single-centric, single-arm pilot study to evaluate the safety and effectiveness of *Swasa Kudori Chooranam* (SKC) in the management of *Swasa Kaasam* (bronchial asthma) - a study protocol. Int J Pharm Sci & Res 2025; 16(1): 167-74. doi: 10.13040/IJPSR.0975-8232.16(1).167-74.