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Protocol for an open-label randomized controlled study evaluating *Agastya Haritaki Rasayana* and *Gudardraka* in the management of *Kaphaja Kasa* (wet cough) in children.

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ABSTRACT

Background: Recurrent respiratory ailments and cough are common reasons for seeking medical assistance in children. The primary characteristic observed in *Kaphajakasa* is cough accompanied with *Ghana* (thick) and *Snigdha* (sticky) phlegm, *Shveta* (white) coloration, *Kapha-nishteevana* (expectoration), and *Vakshasam-poornata* (chest packed with phlegm) etc. Ayurveda offers effective treatments for the management of persistent respiratory ailments, including cough. *Agastya Haritaki Rasayana* is a renowned classical formulation utilized in the management of *Panchvidha* (the five Ayurvedic classifications) *Kasa*. *Gudardraka* is also a classical formation for the management of *Kasa*; however, comparative evidence in pediatric populations is insufficient. Objectives: To compare the efficacy and safety of *Agastya Haritaki Rasayana* and *Gudardraka* in the management of *Kaphaja Kasa* (wet cough) in children aged 8–12 years. Methods: An open-label, randomized controlled clinical study is designed with 124 children fulfilling diagnostic criteria of *Kaphaja Kasa* in classics. Participants will randomly be allocated to receive either *Agastya Haritaki Rasayana* or *Gudardraka*, both administered in a dose of 5 g/day (2.5 g twice daily) for 20 days with warm water. The primary outcome was the change in *Kaphaja Kasa* symptoms grading score; secondary outcomes included improvement in Leicester Cough Questionnaire scores and safety assessed by hematological parameters. Statistical analysis will be performed using SPSS, applying t-tests and non-parametric equivalents as appropriate. Results: It is anticipated that *Gudardraka* will demonstrate significant therapeutic benefit compared with *Agastya Haritaki Rasayana* in reducing the severity of *Kaphaja Kasa* and improving the quality of life among children. Conclusion: The study will provide comparative clinical evidence on two classical Ayurvedic formulations for *Kaphaja Kasa* (pediatric wet cough), contributing to safe, effective, and evidence-based Ayurvedic respiratory care.

INTRODUCTION:

Cough is one of the most common reasons for pediatric consultations worldwide, with an estimated 25% prevalence among children [i],[ii] . Wet cough (also termed productive cough) is characterized by the expectoration of mucus or phlegm from the lower airways, often accompanied by nasal congestion, throat irritation.[iii]. In children, a wet cough with a duration of less than 14 days is typically acute and most commonly caused by viral upper respiratory tract infections, acute bronchitis

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etc.[iv]. Such episodes are usually self-limiting and resolve spontaneously as mucociliary clearance improves. However, during this acute period, the accumulation of mucus and inflammation in the bronchial passages can cause distress, disturbed sleep, decreased appetite, and reduced quality of life. In the Ayurvedic perspective, a wet or productive cough of recent onset correlates with *Kaphaja Kasa,* wherein aggravated *Kapha Doṣa* obstructs the *Pranavaha Srotas*, leading to *Bahula Kaphasthivana* (frequent thick expectoration), *Pinasa* (nasal discharge), *Sthaimitya* (heaviness of chest), and *Mandagni* (weak digestion)[v],[vi]. Thus, the acute phase of wet cough (<14 days) reflects *Kapha-dominant pathology* requiring *Kaphaghna*, *Dipana*, and *Pacana* interventions to restore normal airway function. Children, being *Kapha*-dominant by nature, are more susceptible to respiratory illnesses such as *Kaphaja Kasa*. Untreated or recurrent episodes may progress to protracted bacterial bronchitis or other chronic respiratory disorders. *Agastya Haritaki Rasayana*, mentioned in Ayurveda classics is a classical polyherbal Rasayana formulation traditionally used for the management of *Kasa* (cough) and *Swasa* (respiratory disorders). It possesses *Deepana, Pachana, Rasayana*, and *Kapha-Vata-Shamana* properties, and has been recommended as a rejuvenative and curative medicine for chronic respiratory diseases. [vii],[viii] .*Gudardraka,* from *Sahasrayoga,* combines jaggery and ginger with Trikatu and aromatic herbs, exhibiting mucolytic, expectorant, and broncho dilatory effects [ix]. This clinical study aims to evaluate and compare these formulations to establish evidence-based Ayurvedic management for pediatric wet cough.

OBJECTIVES:

The primary objective of the study is to evaluate the comparative efficacy of *Agastya Haritaki Rasayana* and *Gudardraka* in relieving the clinical features of *Kaphaja Kasa* in children. The secondary objectives are to assess the improvement in quality of life through the Leicester Cough Questionnaire and to evaluate the safety profile of both interventions through clinical and laboratory assessments.

Trial design and Setting:

This study is designed as open-label, randomized, parallel-group clinical trial. Eligible participants will be randomized in a 1:1 ratio to receive either of the interventions. The study will be conducting at the Central Ayurveda Research Institute (CARI), New Delhi, under the Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Government of India.

Eligibility Criteria:

Inclusion Criteria:

Children aged between 8 and 12 years, irrespective of gender, religion, or socio-economic status, will be included in the study. Participants presenting with one or more clinical features of *Kaphaja Kasa* of less than 14 days' duration consider as eligible. The characteristic features observed included *Snigdha* (unctuous), *Ghana* (solid), and *Bahal Kaphasthivana* (productive cough with expectoration). Associated manifestations such as *Peenasa* (nasal discharge), *Chardi* (vomiting), *Alparuk in Uras* (mild chest pain), *Kanthaupalepa* (coating in the throat), *Mandagni* (reduced appetite), and *Sampoornavakshas* (fullness in the chest) will also take into account. Only those children whose parents or legal guardians provided written informed consent for participation will be enrolled in the study.

Exclusion Criteria:

Children suffering from any chronic illness of other systems, or those presenting with a cough persisting for 14 days or more, will be excluded. Subjects diagnosed with congenital anomalies, asthma, pulmonary tuberculosis, chronic obstructive pulmonary disease (COPD), or any other chronic debilitating condition will not be considered for inclusion. Children with neurological or hereditary disorders will also be excluded. Additionally, any participant with a condition that, in the opinion of the investigator, could compromise the safety of the participant or affect the validity of the study outcomes will be excluded from the trial.

Methodology and Interventions:

A total of 124 children of either gender aged 8–12 years fulfilling the inclusions of *Kaphaja Kasa* will be enrolled after obtaining informed consent from their parents or guardians. Participants will be randomly allocated into two groups of 62 each. Group A will receive *Agastya Haritaki Rasayana* and Group B will receive *Gudardraka*, both administered in a dose of 2.5 g twice daily for 20 days. The formulations will be prepared in GMP-certified pharmacies following classical Ayurvedic procedures. Patients will be followed up on the 10th, 20th, and 35th days to assess therapeutic response and monitor adverse events.

Withdrawal Criteria:

Participants could be withdrawn from the study either at their own request or at the discretion of the investigator if deemed necessary. Discontinuation of participation will be considered under the following circumstances: the occurrence of any serious adverse event rendering the participant unable to perform activities of daily living; the development of any acute illness requiring hospitalisation; noticeable worsening of the participant's condition during the course of the study; or the participant's unwillingness to continue in the trial.

Outcome Measures:

The primary outcome will be the change in the *Kaphaja*

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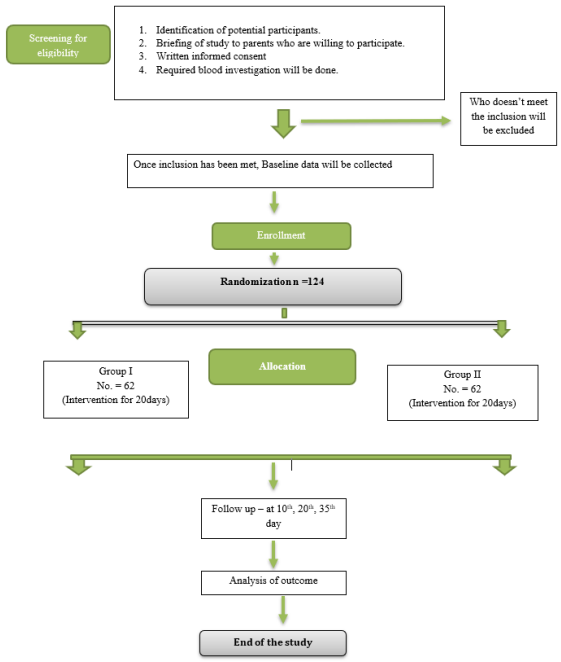
Kasa grading score from baseline to end of the trial. Secondary outcomes include change in Leicester Cough Questionnaire scores, changes in hematological (CBC, LFT, KFT), and Peak Expiratory Flow Rate (PEFR). Safety will be assessed by monitoring adverse events throughout the study period.



Sample Size Determination:
The sample size for the present study was calculated based on a two-proportion hypothesis test, assuming large sample approximation with equal allocation between the two study arms. The expected proportion of improvement in Group I was taken as 0.70, while that in Group II was assumed to be 0.90, giving a risk difference of –0.20. With the power of the study set at 80% and a two-sided alpha error of 5%, the required sample size was calculated to be 62 participants in each arm. Thus, the total sample size for the study is 124 participants.

Statistical Analysis:
Collected data will be analyzed using SPSS software. Continuous variables will be presented as mean ± standard deviation, and categorical data as percentages. Within-group comparisons will be made using paired t-tests, and between-group differences using independent t-tests or non-parametric equivalents. Statistical significance will be set at $p < 0.05$.

Randomization:
Participants meeting eligibility criteria will be randomly allocated in a 1:1 ratio to receive either *Agastyaharitaki* or *Gudardraka*. Randomization will be implemented using a computer-generated sequence to ensure unbiased allocation.

Ethical Considerations:
The study has been approved by the Institutional Ethics Committee of Central Ayureda Research institute, New Delhi and prospectively registered with the Clinical Trials Registry-India (CTRI/REF/2025/02/099430). Written informed consent will be obtained from parents or legal guardians before participation. Confidentiality and safety will be maintained throughout the trial.

Consent and Confidentiality:
Informed written consent will be obtained from parents or legal guardians prior to trial procedures. Where applicable, verbal assent will also be obtained from children aged seven and above, in a language they comprehend.

CONFLICT OF INTEREST:
Investigators declare no financial or personal conflicts of interest related to the trial or its outcomes.

DISCUSSION:
Ayurveda offers several *Rasayana* and *Kapha-Vata Shamana* formulations for respiratory disorders in children. Classical Ayurvedic literature extensively describes *Agastya Haritaki Rasayana* as one of the most important formulations for the management of respiratory disorders such as *Kāsa* (cough), *Śvāsa* (dyspnoea), and *Kṣaya* (emaciation). It is mentioned in *Ashtāṅga Hṛdaya* as a Rasayana specifically indicated in *Kaphaja* and *Vataja Kasa* due to its *Deepana* (digestive stimulant), *Pachana* (metabolic enhancer), *Srotoshodhana* (channel-cleansing), and *Kapha-Vata-Shamana* (pacifying) properties[x] ,[xi].Similarly, *Charaka Samhita* and *Sushruta Samhita* highlight the role of *Haritaki*-based Rasayana formulations in promoting respiratory health and preventing recurrent respiratory infections[xii],[xiii] The formulation's ingredients such as *Pippali (Piper longum)*, *Gokshura (Tribulus terrestris)*, *Agni-mantha (Clerodendrum phlomidis)*, and *Dashamoola* exhibit proven anti-inflammatory, mucolytic, and bronchodilatory actions[xiv],[xv] ,[xvi].Modern reviews reaffirm these classical indications. Pharmacodynamic aspects of *Agastya Haritaki Rasayana* concluded that it acts as an immunomodulatory *Rasayana* useful in chronic respiratory tract conditions including *Kasa* and *Shwasa* [xvii].Classical Ayurvedic compendia such as *Sahasrayoga* (*Lehya Prakarana*), *Charaka Samhita*, and *Ashtāṅga Hṛdaya* describe *Gudardraka,* a formulation combining *Guda* (jaggery) and *Ardraka* (fresh ginger juice), as a potent expectorant and *Kaphaghna* (Kapha-alleviating) remedy in *Kaphaja Kāsa* and other respiratory disorders[xviii] ,[xix], [xx]. The *Ardraka Swarasa* acts as a *Deepana* and *Pachana Dravya*, promoting digestion of *Ama* (metabolic toxins) and facilitating clearance of mucus from the respiratory tract. *Guda*, being *Madhura* and *Snigdha* in nature, enhances palatability, stabilizes the formulation, and exerts mild demulcent and nutritive actions, which soothe the irritated throat and bronchi

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[xxi]. The pharmacological profile of *Zingiber officinale* (Ardraka) demonstrates proven anti-inflammatory, bronchodilatory, mucolytic, and antimicrobial actions that correlate well with the Ayurvedic understanding of *Kaphaja Kāsa*[xxii] ,[xxiii], [xxiv].Modern analytical and pharmacological studies have confirmed that Gudardraka and related ginger–jaggery preparations possess potent antioxidant and immunomodulatory properties, supporting mucociliary clearance and improving respiratory comfort[xxv],[xxvi] . Therefore, *Gudardraka* serves as an effective, safe, and palatable option in managing *Kaphaja Kāsa*, particularly in pediatric patients. In comparison of *Agastyaharitaki Rasayana*, *Gudardraka* has limited high-quality clinical trials. However, there is documentation of its use and pharmacology but fewer comparative study are available.

Therefore, conducting a comparative study will help bridge the existing knowledge gap by determining which of the two interventions offers superior efficacy, safety, and patient acceptability in the management of *Kaphaja Kasa* in children."

Author contributions:
SDS, AK, SS designed the methodology, drafted the study protocol and study plan. SS, SDS, AK, BG, AT critically reviewed and refined the protocol; SS, BG handled ethics (IEC) and CTRI registration. SS, BG coordinated the project's logistical execution; SS prepared the initial full draft of the manuscript. SS, SDS, AK, BG, AT addressed peer reviewer comments and revised the final version. All authors reviewed and approved the final version and accept accountability for their respective contributions.

CONCLUSIONS:

This trial is designed to generate clinical evidence for these time-tested Ayurvedic formulations, potentially supporting their integration into modern pediatric respiratory care. The study may also establish standard outcome measures and safety profiles, encouraging future large-scale trials.

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TIMELINE/GANTT CHART

Clinical Assessment and Investigation (Schedule of Events and Laboratory tests per patient)

Visit	Baseline (0 day)	10th day (±3days)	20th day (±3days)	35th day (±3days)
Informed Consent	X			
Demographics	X			
Inclusion and Exclusion Criteria	X			
Medical History	X			
Concomitant illness	X			
Clinical Examination	X	X	X	X
Randomization	X			
Kaphaj Kasa Grade score	X	X	X	X
Leicester QoL questionnaire	X		X	X
Study Drug Dispensation	X			
Adverse Event Assessment		X	X	X
CBC, KFT, LFT,Xray(If required)	X		X	

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