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# EFFICACY OF BHARANGYADI SYRUP IN THE INTERMITTENT PHASE OF BRONCHIAL ASTHMA IN CHILDREN: A RANDOMIZED COMPARATIVE CONTROLLED CLINICAL STUDY PROTOCOL

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## ABSTRACT

**Introduction:** *Tamaka Swasa*, as defined in *Ayurveda*, is a chronic disorder of the *Pranavaha Srotasa* involving *Vata* and *Kapha Dosha* and is comparable to bronchial asthma in contemporary medicine. Childhood bronchial asthma is a major public health concern due to recurrent episodes, reduced quality of life, and long-term dependence on conventional medications that may cause adverse effects. The Centres for Disease Control and Prevention reports that about 7.5% of children aged 5–11 years are affected by bronchial asthma. While modern management relies on bronchodilators and anti-inflammatory drugs, *Ayurveda* offers *Swasahara* and *Rasayana*

formulations to relieve symptoms, enhance *Bala*, and modify disease progression. This study aims to evaluate the comparative effectiveness of *Bharangyadi* Syrup and *Vasa Avaleha* Syrup in children with *Tamaka Swasa*. **Methods:** A randomized, controlled, parallel-group clinical trial will include 64 children aged 5–10 years with intermittent *Tamaka Swasa*. Participants will be equally divided into two groups and will receive either *Vasa Avaleha* Syrup or *Bharangyadi* Syrup for 60 days. Outcomes will be assessed using *Ayurvedic* symptom scoring, MPASS, PEFR, and C-ACT. **Expected Results:** Both formulations are expected to alleviate symptom severity and recurrence, with *Bharangyadi* Syrup anticipated to provide similar or enhanced benefits while also promoting better compliance. **Conclusion:** The study may validate a child-friendly *Ayurvedic* approach for pediatric bronchial asthma management.

**Keywords: *Tamaka Swasa*, Bronchial Asthma, *Bharangyadi* Syrup, *Vasa Avaleha* Syrup, Pediatric *Ayurveda*, Randomized Controlled Trial**

## 1. INTRODUCTION:

*Swasa Roga* is characterized by pathological alterations in the respiratory system leading to labored breathing, described as *Bhastrikadhmanasame*—the chest moving like a blacksmith's bellows, endangering life **[1]**. *Sushruta Samhita* explains that when the normal flow of *Prana Vayu* is disturbed and its movement is hindered by *Kapha*, it causes difficulty in breathing, leading to the development of *Swasa Roga* **[2]**. *Charaka Samhita* classifies five types—*Maha*, *Urdhva*, *Chinna*, *Tamaka*, and *Kshudra Swasa* **[3]**, identifying *Tamaka Swasa* as *Yapya* **[4]**. The term *Tamaka Swasa* is composed of two words: *Tamaka* and *Swasa*. The word *Tamaka* is derived from the *Dhatu* '*Tamalganou*,' which translates to 'Sadness' (Panini). According to *Vachaspatyam*, the term '*Swasa'* originates from the root word '*Shwas' Dhatu,* with the application of *Ghanj Pratyaya*. This indicates both *Vayu Vyapara* and *Roga Bheda* **[5]**. Aggravated *Vata*, due to exposure to causative factors, leads to its *Pratiloma gati* or reverse movement. The vitiated *Vata* travels through channels and reaches the head and neck region, exacerbating the regional *Kapha* by increasing epithelial secretion and producing *pinasa*. These secretions, or *malarupi Kapha*, obstruct the air passage and create a *ghurgurshabda* or wheezing sound **[6]**.

Bronchial asthma closely resembles *Tamaka Swasa* and is a major pediatric health issue. The Centers for Disease Control and Prevention reports 7.5% prevalence in children aged 5–11 years **[7]**. In Western

India, this rate rises to 9% for children within the same age group **[8]**. As stated by the Global Initiative for Asthma (GINA) in 2018, asthma is a diverse condition typically characterized by persistent inflammation in the airways. It is identified by a history of respiratory issues such as wheezing, difficulty breathing, chest tightness, and coughing, which can vary over time in both frequency and intensity, along with irregular airflow during exhalation **[9]**. There are four levels of asthma severity: intermittent, mild, moderate, and severe. Treatment and management vary based on the specific stage of asthma. Intermittent asthma is characterized by symptoms occurring less than twice a week and nighttime awakenings happening fewer than two times a month **[10]**.

Conventional management (β2-agonists, theophylline, glucocorticosteroids) lacks cure and may cause long-term adverse effects. Recurrent attacks lead to *Dhatu Kshaya* and *Bala Kshaya* **[11]**. Classical forms (*choorna, kashaya, vati, avaleha*) have limited pediatric compliance **[12]**. Hence, syrup formulations are preferred. *Bharangyadi Kashaya* **[13]**, containing *Bharangi, Vasa, Pippali, Kantakari, Shunthi, Guduchi, Haridra, Dhanyaka,* and *Maricha*, possesses mucolytic, bronchodilatory, anti-inflammatory, and properties. Therefore, this study evaluates *Bharangyadi* Syrup versus *Vasa Avaleha* Syrup in pediatric *Tamaka Swasa*.

## 2. METHODS

### 2.1.Study design and setting

This study will employ a randomized comparative controlled interventional clinical design. The research will be conducted at *Kaumarabhritya* Outpatient department/ Inpatient department, Khemdas Hospital, Parul Institute of Ayurved & Research, Vadodara, Gujarat, India with participant recruitment to be carried out using simple random sampling. The proposed study plan, i.e. consort diagram, is mentioned in **Figure 1**.

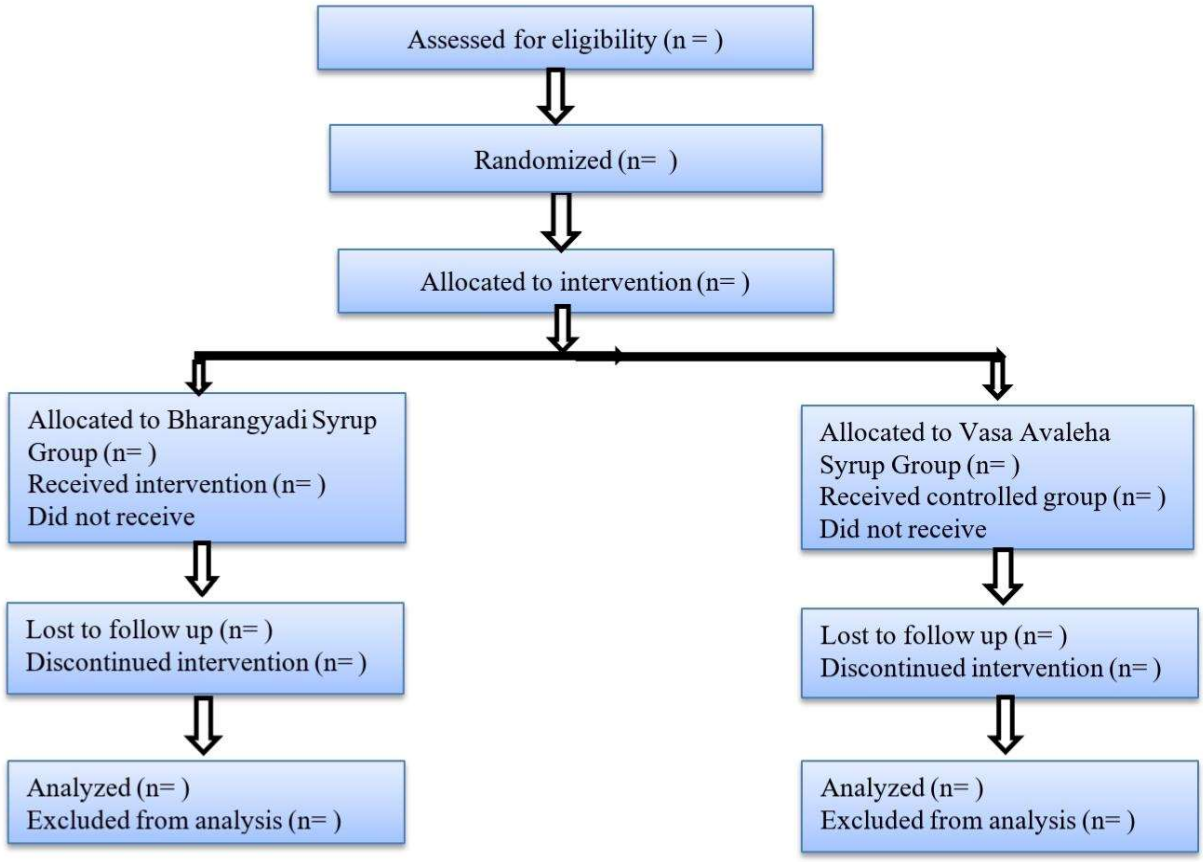


**Figure 1: Proposed Study plan**

**2.2. Eligibility Criteria**:

The participants in the study will be chosen based on these criteria: they must be children aged 5 to 10 years at the time of enrollment, irrespective of gender or socio-economic background; they should have a diagnosis of *Tamaka Swasa* according to traditional *Ayurvedic* clinical features; they will be clinically diagnosed with intermittent phase bronchial asthma; and their parents or legal guardians must provide written informed consent along with the child's assent, demonstrating their willingness to comply with the treatment protocol and attend all scheduled follow-up appointments.

The exclusion criteria will include individuals with other types of *Swasa roga*; those diagnosed with mild persistent, moderate persistent, or severe persistent bronchial asthma; children experiencing acute exacerbations or status asthmaticus that necessitate emergency medical treatment; patients with related systemic diseases such as tuberculosis, pneumonia, or congenital heart disease; individuals suffering from chronic pulmonary issues like chronic obstructive pulmonary disease (COPD), pulmonary

fibrosis, or pulmonary hypertension; participants who do not provide consent; and any other medical or clinical condition that, in the investigator's opinion, would make the subject unsuitable for participation in the study.

**2.3.Interventions**

The study will consist of two intervention groups, with participants randomly assigned in a 1:1 ratio. Group A (Control Group) will be administered *Vasa Avaleha* Syrup orally at a dosage of 5 ml three times daily (TDS) following meals. Group B (Trial Group) will receive *Bharangyadi* Syrup orally at the same dosage of 5 ml three times daily (TDS) after meals. Both groups will participate in their respective interventions for a period of 60 days.

**2.4.Outcome measures with timelines**

The primary outcome measures of the study will concentrate on assessing the intensity and occurrence of classical symptoms linked to *Tamaka Swasa*. This will be evaluated using the WHO-recommended *Ayurvedic* symptom scoring system **[14]**, which will include *Swasakrichrata* (dyspnea), *Kasa* (cough), *Kapha Nistivanam* (expectoration), *Pinasa*, the frequency of *Swasa Vega*, *Parshva Shoola*, and *Ushnabhinandati* will be recorded at baseline (0th day), as well as on the 15th, 30th, and 45th days (during treatment), and at the end of the treatment period (60th day). Furthermore, the clinical management of bronchial asthma (*Tamaka Swasa*) will be tracked using the Modified Pediatric Asthma Scoring System (MPASS) **[15]**. MPASS will evaluate essential clinical parameters such as respiratory rate, wheezing, use of accessory muscles, oxygen saturation, and the degree of respiratory distress, thus offering an objective and standardized assessment of asthma severity in children. The MPASS score will be recorded at baseline (0th day), as well as on the 15th, 30th, and 45th days (during treatment), and at the end of the treatment period (60th day) to assess the therapeutic effectiveness of the study interventions in reducing the severity and frequency of asthma symptoms.

The secondary outcome measures will include the evaluation of Peak Expiratory Flow Rate (PEFR) and Childhood Asthma Control Test (C-ACT) **[16]** scores to evaluate clinical control of asthma and to monitor the treatment response over time will be evaluated at baseline ($0^{th}$ day) and at the end of treatment ($60^{th}$ day). Additionally, other secondary outcomes will involve monitoring and documentation of adverse drug reactions (ADRs) to establish the safety profile of the study medications.

**2.5.Sample size**:

The sample size of 64 participants (32 per group) was calculated using the Cochran formula, based on a prevalence rate of 9% with a 95% confidence level.

## 3. DATA COLLECTION AND STATISTICAL ANALYSIS PLAN

Clinical data will be systematically gathered utilizing a pre-structured Case Report Form (CRF), where all observations prior to and following treatment will be recorded at specified intervals. Both subjective and objective measures will be evaluated at baseline and during planned follow-up appointments in line with the study protocol. Any missed doses, adverse drug reactions (ADRs), or deviations from the protocol will be duly noted and reported throughout the study period. The gathered data will be input into Microsoft Excel and analyzed with suitable statistical software. Continuous variables will be represented as mean ± standard deviation (SD) for data that follows a normal distribution, and as median with interquartile range (IQR) for data that does not follow a normal distribution. Categorical variables will be shown as frequencies and percentages. Comparisons at baseline between the two study groups will be conducted using the independent samples t-test for continuous variables that are normally distributed and the Mann–Whitney U test for those that are not. Categorical variables will be examined using the Chi-square test or Fisher's exact test, as appropriate.

The primary outcomes, which will include the reduction in severity and frequency of classical symptoms of *Tamaka Swasa* evaluated through the WHO-recommended *Ayurvedic* symptom scoring (covering *Swasakrichrata*, *Kasa*, *Kapha Nistivanam*, *Pinasa*, frequency of *Swasa Vega*, *Parshva Shoola*, and *Ushnabhinandati*) and the Modified Pediatric Asthma Scoring System (MPASS), will be assessed at baseline ($0^{th}$ day), $15^{th}$ day, $30^{th}$ day, $45^{th}$ day, and at the conclusion of treatment ($60^{th}$ day). Within-group comparisons will be performed using the paired samples t-test for normally distributed data or the Wilcoxon signed-rank test for non-normally distributed data, while between-group comparisons will be carried out using the independent samples t-test or Mann–Whitney U test, as relevant.

The secondary outcome measures, which will encompass Peak Expiratory Flow Rate (PEFR), Childhood Asthma Control Test (C-ACT) scores, evaluation of improvements in sleep, appetite, and daily activities, will be evaluated at baseline ($0^{th}$ day) and at the end of treatment ($60^{th}$ day). These outcomes will be analyzed using comparable within-group

and between-group statistical tests based on the distribution of the data.

A comprehensive intention-to-treat (ITT) methodology will be applied for all statistical evaluations. Any missing data will be handled using the Last Observation Carried Forward (LOCF) technique. A two-tailed p-value of less than 0.05 will be considered statistically significant for the entirety of the analysis.

## 4. DISCUSSION

This study will compare *Bharangyadi* Syrup and *Vasa Avaleha* Syrup in managing *Tamaka Swasa* in children during the intermittent phase of bronchial asthma. It will evaluate their therapeutic efficacy in correcting *Vata–Kapha* imbalance, restoring *Pranavaha Srotas* function, and relieving airway obstruction. Both clinical symptoms and objective pulmonary parameters will be assessed for comprehensive evaluation. Supported by emerging evidence of their anti-asthmatic, anti-inflammatory, bronchodilatory, and immunomodulatory properties, these formulations will demonstrate promising potential as safe, effective, and integrative options for long-term pediatric asthma management.

### 4.1.Role of Bharangyadi syrup in Tamaka swasa

Syrup will function through a synergistic *Rasa-Panchaka* mechanism, showcasing *Vatakaphahara, Deepana, Pachana*, and *Vatanulomana* properties that are essential for managing *Tamaka Swasa*. By improving *Jatharagni, Rasagni, and Bhutagni,* its *Deepana-Pachana* action will eliminate *Ama*, a key factor in the pathogenesis. The *Shothahara* effect will help relieve *Srotorodha* in the *Pranavaha Srotasa* caused by *Sama Vata*.

Ingredients such as *Bharangi, Pippali, Shunthi, Maricha, Haridra,* and *Kantakari* primarily pacify *Vata* and *Kapha*, while *Guduchi* and *Dhanyaka* will contribute *Tridoshahara* action. *Pippali* and *Shunthi* will facilitate *Vatanulomana*, improving airflow and reducing dyspnea. The combined *Swasa-Kasa-Shothahara* properties will directly address core asthma symptoms. Pharmacologically, the formulation will demonstrate antiallergic (*Haridra, Bharangi, Guduchi*), anti-inflammatory (*Haridra, Guduchi, Maricha, Kantakari, Pippali, Shunthi*) **[16]**, bronchodilatory and expectorant (*Vasa, Pippali*) **[17]**, antispasmodic (*Vasa, Dhanyaka*), antitussive (*Vasa, Shunthi*), and immunomodulatory (*Pippali, Guduchi*) **[17]** effects, thereby supporting its therapeutic role in pediatric bronchial asthma **[18]**.

### 4.2.Vasa Avaleha Syrup in Tamaka Swasa

*Vasa Avaleha* is a classical formulation indicated in *Tamaka Swasa*, acting primarily through its *Vata-Kaphaghna* properties to correct doshic imbalance. The *Sukshma* and *Tikshna* qualities of *Vasa* (*Adhatoda vasica*), *Pippali* (*Piper longum*), and *Madhu* facilitate *Kaphanihsarana*, clearing *Kapha Upalepa* from the *Kantha* and *Ura*, thereby relieving airway obstruction. *Vatahara* ingredients such as *Sita*, *Go-Ghrita*, and *Pippali* will promote *Vatanulomana* and pacify disturbed *Prana* and *Apana Vayu*. *Go-Ghrita* and *Pippali* will also enhance *Agni*, improving digestion and metabolism, while their *Rasayana* properties strengthen immunity and reduce recurrence. *Vasa*, the chief ingredient, is traditionally indicated in *Swasa*, *Rajayakshma, Raktapitta, Shotha*, and *Jwara*. Its alkaloids, vasicine and vasicinone, will exhibit potent bronchodilatory effects, with vasicinone reported to be significantly more effective than aminophylline in bronchial asthma. Additionally, *Pippali* will enhances drug bioavailability, sustaining therapeutic action and augmenting the overall anti-asthmatic efficacy of the formulation **[17, 18]**.

## 5. STRENGTHS AND LIMITATIONS:

The study design will employ a randomized comparative clinical approach to evaluate the therapeutic efficacy of *Bharangyadi* Syrup in comparison to *Vasa Avaleha* Syrup for the treatment of *Tamaka Swasa* in children, thereby enabling a systematic analysis of the clinical outcome variations between the two formulations. The protocol will encompass both subjective and objective assessment tools for outcomes, incorporating validated clinical scoring systems such as the Modified Pediatric Asthma Scoring System (MPASS) and Peak Expiratory Flow Rate (PEFR) measurements, which will enhance the reliability and credibility of the study findings. Furthermore, there may be a possibility that the inclusion of pediatric-friendly syrup formulations will improve acceptability and adherence to treatment, resulting in better therapeutic compliance and more accurate outcome evaluations.

The study may face specific limitations, such as the lack of blinding, since the unique features and sensory qualities of *Ayurvedic* treatments will render blinding unfeasible, potentially leading to performance bias. To mitigate this impact, outcome evaluation and data analysis will be performed using standardized assessment techniques and objective criteria. The single-center design and the relatively small sample size may restrict the applicability of the results to larger populations. Furthermore, the brief follow-up period will limit the capacity to evaluate long-

term disease management, recurrence rates, and ongoing therapeutic effectiveness.

## 6. FUTURE IMPLICATIONS :

If the study uncovers significant clinical benefits, it may establish a foundation for larger multicentric trials with extended follow-up periods to evaluate long-term efficacy and safety. Future investigations that incorporate objective inflammatory and immunological biomarkers could provide deeper insights into the mechanisms by which *Ayurvedic* therapies function. Positive outcomes could enhance the development of integrative *Ayurveda*-based approaches for managing pediatric bronchial asthma and related chronic respiratory issues.

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