DOI: 10.7860/JCDR/2026/82200.23620

Research Protocol

Ayurveda Section

Evaluation of the Comparative Efficacy of *Dugdhika* (*Euphorbia prostrata W. Aiton*) Inhalation versus Salbutamol in the Management of *Tamaka Shwasa* (Bronchial Asthma): A Research Protocol

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ABSTRACT

Introduction: *Tamaka Shwasa* is an Ayurvedic respiratory disorder caused by vitiated *Prana Vayu* and aggravated *Kapha*, often worsened by dust, smoke, cold, and exertion. It resembles bronchial asthma, which affects around 300 million people globally and 15-20 million in India. Modern treatment includes bronchodilators like Salbutamol, while Ayurveda herbs like *Dugdhika* (*Euphorbia prostrata*), known for its *Shwasahara* and *Kaphahara* effects in respiratory conditions.

Aim: Evaluation of comparative efficacy of inhalation of *Dugdhika* (*Euphorbia prostrata w.Ait*) versus Salbutamol in the management of *Tamaka Shwasa* (Bronchial asthma).

Need of the study: Salbutamol provides rapid bronchodilation in bronchial asthma, but its repeated use is associated with undesirable adverse effects and limited long-term acceptability. *Dugdhika* (*Euphorbia prostrata*), described in Ayurvedic literature as *Shwasahara* and *Kaphashamaka*, exhibits bronchodilator and smooth muscle relaxant actions in experimental studies. Hence, the present study is required to evaluate *Dugdhika* as a potentially safe, cost-effective, and evidence-based alternative for the immediate management of *Tamaka Shwasa* (bronchial asthma).

Materials and Methods: The Mahatma Gandhi Ayurved College Hospital and Research Centre in Salod (H), Wardha, Maharashtra, India, will host an eight-month randomised single blind standard controlled equivalency clinical trial study from October 2025 to May 2026. The present study consists of 110 patients who fit the requirements for inclusion, divided into two groups of 55 at random. Group 2 will get an inhalation stat of Salbutamol, whereas Group 1 will receive an inhalation stat of *Dugdhika.* Assessments will be conducted before and after 20 minutes of giving inhalation. Outcomes will be measured using peak expiratory flow rate, spirometry, breathlessness (Dyspnoea).

Keywords: Ayurvedic medicine, Bronchodilator agents, Respiratory therapy

INTRODUCTION

Tamaka Shwasa is a type of *Shwasa Roga* that affects the *Pranavaha Strotas* characterised by dyspnoea, prolonged expiration, sputum production and wheezing [1]. *Tamaka Shwasa* is one of the five types of *Shwasa Roga* that *Ayurveda* has recognised, and it is categorised as a *Yapya Vyadhi* (palliative). *Tamaka Shwasa* refers to a *"Swatantra Vyadhi* i.e., independent disease entity and having its own aetiology, patho-physiology, and management" [2]. It is clear that breathing problems arise or are exacerbated by exposure to smoke, dust, or wind, as well as by consuming cold water or other substances and exercising. Ama Pradosha is said to be a contributing component in *Shwasa* roga [3]. According to Acharya Sushruta, the normal Prana Vayu gets vitiated by aetiological factors and its movement is obstructed by Kapha dosha. This leads to increased and laboured breathing, results in *Shwasa* Roga [4]. It has a strong correlation to bronchial asthma. Its pathophysiology includes chronic inflammation of the airways, leading to hyperresponsiveness, bronchoconstriction, mucus hypersecretion and culminating in intermittent episodes of airflow obstruction [5]. Wheezing, dyspnoea, tightness in the chest, and coughing, especially throughout the night or early morning, are frequent symptoms of this inflammation. These episodes generally correspond to a broad, varying constriction of airflow, which is often reversible with therapy or on its own [6].

According to World Health Organisation (WHO) estimates, 300 million individuals worldwide are thought to have bronchial asthma at the moment. There are 15-20 million asthmatic individuals in India, according to data on prevalence. Because of smoking, pollution, and other environmental variables, prevalence is higher in urban regions than in rural ones [7]. The aetiological factor of bronchial asthma includes genetic predispositions, environmental variables such as allergens, pollutants and respiratory infection, medicines, smoking, anxiety, and psychological problems [8]. Although there are several recognised aetiologies for the illness, the precise aetiopathogenesis is still unknown. This is a chronic condition characterised by lung damage aggravating events and flare-ups that are accompanied by extended, significant paroxysmal dyspnoea episodes and vice versa [9]. In the fight against this illness, modern medicine has made significant strides, including the development of sophisticated antibiotics, corticosteroids, bronchodilators, etc., [10]. The most common medication used in contemporary bronchial asthma therapy is salbutamol. A selective β_2-adrenergic receptor agonist, salbutamol is used to treat acute asthmatic bronchospasm episodes as well as a number of chronic bronchopulmonary disorders [11]. Acharya *Bhavmishra* mentions the plant *Dugdhika* in *Bhavprakash Nighantu*.

दुग्धिका स्वादुपर्णी स्यात्क्षीरा विक्षीरिणी तथा। दुग्धिकोषणागुरू रूक्षा वातलागर्भकारिणी ॥२७८॥ स्वादुक्षीरा कटुस्तिक्ता सृष्टमूत्रमलापहा। स्वादुविष्टंभिनी ष्या कफकोष्ठाकृमिप्रणुत्॥२७९॥ (भा. नि.)[12]

Priyavat sharma describes the plant *Dugdhika* in *Shwasa* roga.

भूदुग्धिकास्वादुरुष्णाकषायाग्राहिणी मता।श्वासवेगप्रशमनीत्वामातीसारनाशिनी॥१२८॥

प्रि.नि. (प्रियव्रतशर्मा) [13]. Modern treatment approaches for bronchial asthma include the use of bronchodilators, corticosteroids, anticholinergic medications, and a number of additional medications

which are associated with dosage dependence and long-term adverse effects [14]. Salbutamol inhalation has common adverse effect which might include headaches, palpitations, and hot flushes [15]. Fortunately, most medications may be inhaled, improving therapeutic selectivity, and lowering systemic side effects for asthma patients. Prednisolone and theophylline, two oral medications, are more problematic. Theophylline has a limited therapeutic window and is ineffective for many people hence its use in therapy is restricted. Oral steroids undoubtedly result in significant morbidity [16]. Medications administered via the inhalation route act fast to provide relief from symptoms during asthma attacks. *Dugdhika* herb is mentioned for management of *Shwasa* in *Priya Nighantu,* which is herbal formulation, hence, relatively safe and animal study conducted on this herb proved its bronchodilator and smooth muscle relaxant action. No study conducted on *Dugdhika* in *Tamaka Shwasa* in human beings. So, the present study is undertaken to evaluate the efficacy of *Dugdhika* in management of Tamak shwasa with the aim of comparing the efficacy of inhalation of *Dugdhika* (*Euphorbia prostrata W.Ait*) versus Salbutamol in the management of *Tamaka Shwasa* (Bronchial asthma).

Study objectives:

- To assess the efficacy of *Dugdhika* inhalation on spirometry and PEFR in *Tamaka Shwasa* (bronchial asthma).
- To assess the efficacy of Salbutamol inhalation on spirometry and Peak Expiratory Flow Rate (PEFR) in *Tamaka Shwasa* (bronchial asthma).
- To compare the efficacy of *Dugdhika* and Salbutamol inhalation on spirometry and PEFR in *Tamaka Shwasa* (bronchial asthma).

Null hypothesis (H_0): *Dugdhika* inhalation is not as efficacious as Salbutamol inhalation in the management of *Tamaka Shwasa* (bronchial asthma).

Alternative hypothesis (H_1): *Dugdhika* inhalation is as efficacious as Salbutamol inhalation in the management of *Tamaka Shwasa* (bronchial asthma).

REVIEW OF LITERATURE

Tamaka Shwasa, one among the five types of *Shwasa Roga*, is described as a *Yapya Vyadhi* in Ayurvedic texts. It is characterised by *Ghurghuraka* (wheezing), *Shwasakrucchata* (dyspnoea), *Pratiloma Shwasa* (difficulty in expiration), and recurrent attacks associated with *Kasa* and *Peenasa*. The disease shows episodic worsening (*Vega*) and partial remission (*Avega*), reflecting chronicity. In *Charaka Samhita*, Chikitsa Sthana 17th chapter, verses 55-62 discuss Tamaka Shwasa in detail. It is mentioned as *Yapya* in nature and predominantly *Vata-Kaphaja* in origin. Charaka highlights clinical features such as increased respiratory distress at night, in cold seasons, and when exposed to dust, and advises therapies including *Vamana*, *Dhumapana*, and *Lepa* [17] *Sushruta Samhita*, in Uttar Tantra (Chapter 52, Verses 8-10), elaborates Tamaka Shwasa under *Shwasa Pratishedha Adhyaya*, emphasising the obstruction of *Pranavaha Srotas* due to *Kapha Avarana* of *Vata*. It recommends therapies like *Nasya*, *Dhuma*, and *Virechana* [18] *Madhava Nidana* provides a succinct yet important description of Tamaka Shwasa in the Uttar Tantra under *Hikka-Shwasa Nidana* (Verse 34). It outlines causes (*Hetu*), premonitory signs (*Purvarupa*), and full-blown symptoms (*Lakshana*), aligning closely with modern pathophysiology of asthma [19]. *Ashtanga Hridaya*, Nidana Sthana, Chapter 5 (Shwasahidhma Nidana), verses 6-10, describes the disease with features like *Shwasa vegena anidra* (insomnia due to dyspnoea), *Krishna vartma* (dark discoloration of eyelids), *Urahshoola* (chest pain), and *Avashyakata of Upashaya-Anupashaya* for differential diagnosis [20]. In *Ashtanga Sangraha*, Tamaka Shwasa is described as a chronic and recurring respiratory disorder caused by *Vata-Kapha* vitiation. The text highlights key symptoms such as laboured breathing, cough, and wheezing, which worsen with cold and dust exposure-paralleling triggers seen in modern asthma. It emphasises the role of lifestyle and environmental factors in disease aggravation and suggests *Shodhana* and *Shamana* therapies for management [21]. From a *Dravyaguna* point of view, *Dugdhika* (*Euphorbia prostrata*) is considered a potent herb for *Shwasahara* and *Kaphavatashamaka* action. In *Bhavaprakasha Nighantu*, Guduchyadi Varga (Shlokas 275-276), *Dugdhika* is mentioned as: "दुग्धिकातिक्तशिताचश्वासकासविषापह", indicating its usefulness in *Shwasa*, *Kasa*, and even *Visha* conditions [22]. *Priya Nighantu*, in Shatapushpadi Varga (Shloka 128), mentions *Bhudugdhika*, a synonym of *Dugdhika*, possessing similar properties [23]. In *Madanpala Nighantu* (Abhayadi Varga, Shloka 198), *Dugdhika* is noted for its use in *Kasa-Shwasa* [24]. *Dravyaguna Hastamalaka*, Dvitiya Khanda, under Eranda Kula (Entry 346), elaborates its *Rasa*, *Guna*, *Virya*, and *Prabhava*, and classifies it as *Vatanulomaka* and *Shothahara*, justifying its respiratory and anti-inflammatory benefits [25]. In modern medicine, Tamaka Shwasa aligns with bronchial asthma, a chronic inflammatory disease of the airways with episodic reversible bronchoconstriction. *Davidson's Principles and Practice of Medicine* (24th ed., p. 499) defines asthma as involving airway hyperresponsiveness, mucosal oedema, and mucus hypersecretion [26]. Management of asthma in the contemporary system includes bronchodilators, corticosteroids, leukotriene antagonists, and mucolytics. Tripathi KD, in Essentials of Medical Pharmacology (8th ed., p. 221), describes drugs used in asthma such as β_2-adrenergic agonists (e.g., salbutamol), anticholinergics, and inhaled corticosteroids [27].

MATERIALS AND METHODS

The present research protocol is a randomised controlled equivalence clinical trial that will be conducted in the Department of Kayachikitsa, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H) Wardha, Maharashtra, India. The current study will be carried out over a period of eight months, from October 2025 to May 2026. The study protocol was approved by the Institutional Ethics Committee (IEC No.: MGACHRC/IEC/Jun-2024/840, dated 7 June 2024). The Clinical Trial Registry-India (CTRI) registration number is CTRI/2024/10/075854 dated 24 Oct 2024. The patient will be recruited into study groups when the researcher has fully explained the study to them and obtained written informed consent in their native tongue. All the personal information about the patients is kept private. Computerised data should be private and access by only research.

Sample size calculation: The sample size was assessed by taking Standard Deviation (SD) into account and comparing the mean values for the major variable, PEFR, before and after the surgical procedure.

Primary variable: PEFR

Mean±SD PEFR score (post-pre)=(265.75-213.57)=52.18

Difference in mean (δ)=52.18

Pooled std.dev.=(72.67+93.83)/ 2=83.25 [28]

Formula using mean difference:

$$n1 = n2 = \frac{(z_\alpha + z_\beta)^2 \sigma^2}{\delta^2}$$

Zα = 1.96 at 5% error & CI at 95%

Zβ = 0.84 = Power at 80%

$$n = \frac{(1.96 + 0.84)^2 (83.25)^2}{(52.18)^2} = 55 \text{ per group.}$$

Inclusion criteria:

- A patient who is willing to take part and provides signed, informed permission;

- Patients of both genders between 20-60 years of age;
- Patient has cardinal sign and symptoms of *Tamaka shwasa* (Bronchial Asthma).

Exclusion criteria:

- Patients suffering from systemic diseases like diabetes, heart disease, renal disease, Chronic Obstructive Pulmonary Disease (COPD), cancer, tuberculosis, status asthmaticus and other major health problems, lactating and pregnant women.

Study Procedure

Random sampling was used with computerised table technique for the sampling procedure and a total sample size of 110 will be included. Patients will be divided into two groups:

Group A (n=55): *Dugdhika* inhalation

Group B (n=55): Salbutamol inhalation

Withdrawal criteria: If there are adverse consequences or if the subject's problems worsen, they will be eliminated from the research. After that, the individuals will receive free treatment until their issues go away.

Drug collection/authentication:

- The raw material (*Dugdhika* Plant) will be collected from herbal garden of MGACH and RC and the drug is identified and validated by the Dravyaguna Department.
- Drug authentication number is MGACH&RC/DG/2025/45
- Salbutamol is procured from authentic source.

Details of drug preparation:

Alcoholic extract of Dugdhika: The panchanga, or whole plant, of *Euphorbia prostrata w.Ait* will be fully dried, identified under a microscope, and processed into a coarse powder. Using alcohol as a solvent, this powder will be put in a filter paper thimble and put in a Soxhlet extractor. The drug's alcohol-soluble components will be extracted using standard protocol. To make the solvent (alcohol) that passes through the Soxhlet siphon colourless, the alcohol in the Soxhlet will be kept slightly under boiling. The resulting extract will be boiled in a water bath in order to thoroughly evaporate the solvent. The separated extract (water soluble fraction) will be stored in amber color bottle experiment [29].

Salbutamol inhalation will be procured from AVBRH pharmacy: The *Dugdhika* inhalation formulation will be standardised to a physiologically acceptable pH of 7.2 and will maintain a near-isotonic osmolarity of 280-300 mOsm/kg, ensuring safety for respiratory administration. The stability assessment will confirm that the formulation remains chemically and physically stable for up to 90 days, with no changes expected to occur in Potential of Hydrogen (pH), osmolarity, colour, odour, or precipitation during storage in amber bottles at room temperature.

pH, osmolality, and stability of the inhalation formulation: The pH of the *Dugdhika* inhalation solution will be selected and controlled based on pharmaceutical development principles, considering pH as a critical quality attribute [30]. In accordance with the United States Pharmacopeia-National Formulary, General Chapter <1151>, inhalation dosage forms will be formulated with appropriate physicochemical characteristics, including pH and osmolality. The osmolality will be maintained within the near-isotonic range (approximately 280-320 mOsm/kg) [31]. Accelerated stability testing will be conducted at 40°C±2°C/75% relative humidity for three months as per established guidelines [32], with assay acceptance criteria defined as ≤10% [33].

Safety evaluation: The safety of *Euphorbia prostrata* (*Dugdhika*) was supported by preclinical evidence from animal studies. In an experimental study conducted on Wistar albino rats, administration of *Euphorbia prostrata* extract at graded doses produced significant bronchodilator and smooth muscle relaxant effects without any signs of acute or chronic toxicity. No mortality or behavioural abnormalities were observed during the observation period. Biochemical parameters related to hepatic and renal functions remained within normal limits, and histopathological examination of vital organs (liver, kidney, lungs, and heart) showed no structural damage. These findings indicate that *Euphorbia prostrata* is pharmacologically active yet well tolerated in animal models.

Safety monitoring: Throughout the intervention period, participants will monitor for any adverse reactions or respiratory discomfort. Clinical safety parameters such as pulse rate, respiratory rate, blood pressure, and Oxygen Saturation (SpO_2) will record. Subjects will specifically observe for signs of bronchospasm, throat irritation, coughing, or allergic manifestations such as rash or pruritus following inhalation. Any adverse event will be documented and managed according to standard medical care.

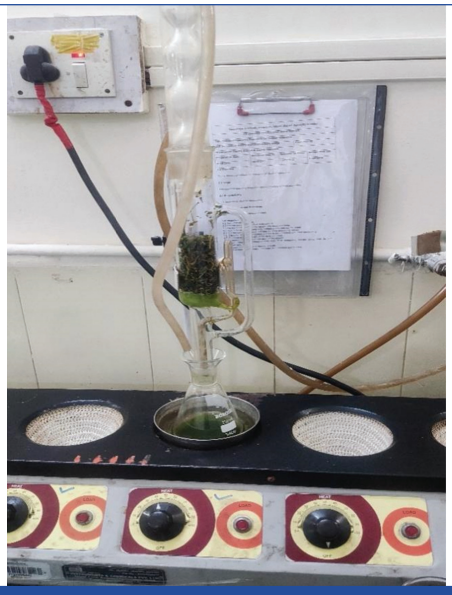
The raw drug *Dugdhika* is shown in [Table/Fig-1].

[Table/Fig-1]: Dugdhika.

The dried and powdered form of *Dugdhika* is depicted in [Table/Fig-2]. The Soxhlet extraction procedure employed for the preparation of *Dugdhika* extract is illustrated in [Table/Fig-3].

[Table/Fig-2]: Dry drug.

Enrolment and intervention schedule: Drugs will be administered stat. Following the intervention, assessments will be made after 20 minutes.



[Table/Fig-3]: Soxhlet extraction.

Execution: The lead investigator will register the participants, and the second investigator will conduct the evaluation. There will be two groups, each consisting of 55 patients.

The posology and grouping for both groups are explained in [Table/Fig-4]. The composition of *Dugdhika* extracted mention in [Table/Fig-5].

Group	Sample size	Intervention	Dose and frequency
A	55	*Dugdhika* inhalation	2.5 mL stat
B	55	Salbutamol inhalation	2.5 mL stat

[Table/Fig-4]: Posology and grouping.

S. No.	Content	Latin name	Part used
1	*Dugdhika*	*Euphorbia prostrata w.Ait*	*Panchang*

[Table/Fig-5]: Composition of *Dugdhika* extract.

The rasapanchaka of *Dugdhika* mention in [Table/Fig-6].

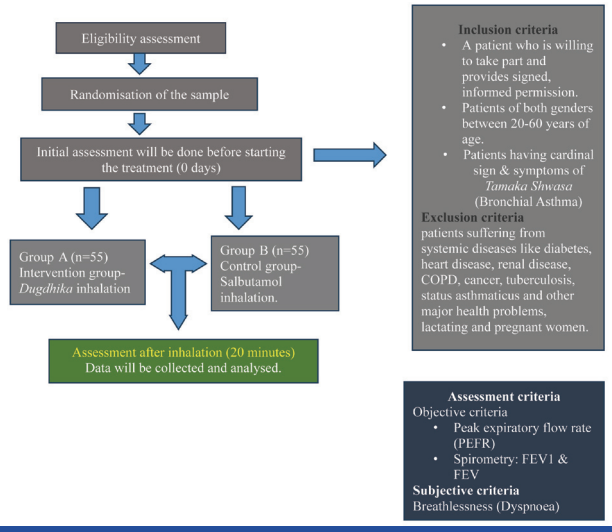
Drug	Rasa	Guna	Virya	Vipaka	Karma
Dugdhika (Euphorbia prostrata w. Ait)	*Katu-Tikta*	*Guru-Ruksha*	*Ushna*	*Katu*	*Kaphashamak*

[Table/Fig-6]: Rasapanchaka of *Dugdhika*.

Storage:

- *Dugdhika* inhalation - Amber colour bottle

The study protocol is illustrated in [Table/Fig-7].



[Table/Fig-7]: Study protocol.

Diagnostic criteria:

- Spirometry
- PEFR
- Breathlessness

Primary outcome:

- Peak expiratory flow rate (PEFR): Mild - >75 %
  - Moderate- 50-74%
  - Severe - <49% [34]

Secondary outcome:

- Spirometry FEV1: Mild - >70 %
  - Moderate - 50 - 69%
  - Severe - <49% [35]

Subjective criteria:

- Breathlessness (dyspnoea)
- Gradation of dyspnoea mention in [Table/Fig-8] [36].

Gradation of dyspnoea		Severity
0	No breathlessness except during strenuous exercise.	Mild
1	Breathless when rushing or ascending an inclined slope.	
2	Breathlessness or the need to pause when walking at your own pace on a level surface may cause you to walk more slowly than persons your own age.	Moderate
3	Stop for breathing after walking hundred meter on a level surface.	Severe
4	Breathless during resting and while putting on or taking off clothes.	

[Table/Fig-8]: Gradation of dyspnoea.

STATISTICAL ANALYSIS

Statistical Package for the Social Science (SPSS) software version 17 will be used to generate all of the results. All demographic variables will be described using descriptive statistics, and for qualitative measurements, frequency and percentage will also be computed. Outcome variables PEFR, spirometry will be tested for significant difference at 5% level using t-test for normal data or alternative non-parametric test. [Table/Fig-9] shows the study protocol's Gantt chart.

Title	Evaluation of comparative efficacy of inhalation of *Dugdhika* (*Euphorbia prostrata w.Ait*) vs Salbutamol in the management of *Tamaka Shwasa* (Bronchial asthma) - A research protocol					
Steps	Q1 (June 2024)	Q2 (December 2024)	Q3 (September 2025)	Q4 (October 2025)	Q5 (February 2026)	Q6 (April 2026)
Approval from IEC						
Review of literature						
Drug preparation						
Enrollment of the patients						
Data collection						
Statistical analysis						
Thesis writing						
Submission						

[Table/Fig-9]: Gantt chart.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Nov 07, 2025
- Manual Googling: Jan 21, 2026
- iThenticate Software: Jan 24, 2026 (1%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Jul 21, 2025**
Date of Peer Review: **Nov 09, 2025**
Date of Acceptance: **Jan 27, 2026**
Date of Publishing: **Jun 01, 2026**