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Protocol for an Open-Labelled Randomised Comparative Clinical Study to Evaluate the Efficacy of *Bharangyadi Madhuka* versus *Talishadi Churna* in the Management of *Tamaka Shwasa* (Bronchial Asthma)

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Abstract: ***Background: Shwasa roga is a term used in classical texts to describe respiratory disorders. Acharyas have classified all respiratory diseases into five types of Shwasa rogas. Tamak Shwasa is one among them. [1] Tamaka Shwasa is usually correlated with bronchial asthma for having a resemblance in clinical signs and symptoms. Among five shwasa rogas Tamak Shwasa represents a significant burden due to its chronicity, recurrent exacerbations, and the adverse effects of conventional bronchodilator and corticosteroid therapies. While various Ayurvedic interventions have been used to manage this condition, there exists a research gap regarding the comparative evaluation of Bharangyadi Madhuka and Talishadi Churna.***
Objective: This study aims to evaluate and compare the clinical efficacy and safety of Bharangyadi Madhuka versus Talishadi Churna in the management of Tamaka Shwasa (Bronchial Asthma).
Methods: This open-labelled, parallel comparative clinical trial will be conducted at a single center. A total of 60 patients, aged 25–60 years and diagnosed with Tamaka Shwasa (corresponding to mild intermittent or mild persistent asthma per NAEPP criteria), will be enrolled. Subjects will be randomly allocated into two equal groups:

- ***Group A (Intervention): [2] Patients will receive Bharangyadi Madhuka at a dose of 6 gm twice daily (BD) after meals, administered with a vishammatra of madhusarpi (in a 2:1 ratio).***
- ***Group B (Comparator): [3] Patients will receive Talishadi Churna at a dose of 6 gm BD after meals with honey.***

The treatment period is 21 days, with follow-up assessments on days 7, 14, and 21 during treatment and further follow-up on days 28, 35, and 42. Outcome assessments include detailed subjective symptom scoring (e.g., frequency, duration, and intensity of dyspnea, cough, and other related symptoms) and objective clinical criteria (such as the presence of wheezing, rhonchi, and accessory muscle use). Laboratory investigations (e.g., Hb, ESR, CRP, AEC, and pulmonary function tests) will be performed at the specified intervals to monitor safety and therapeutic effects. Data analysis will involve computing means, standard deviations, and appropriate statistical tests, with significance set at $p < 0.05$.
Ethical Consideration: All patients will provide written informed consent prior to participation. The protocol has been approved by the Institutional Ethics Committee and will be registered with the Central Trials Registry-India (CTRI). Confidentiality, adherence to ethical guidelines, and appropriate reporting of adverse events will be ensured throughout the study.
Expected Outcome: We hypothesize that Bharangyadi Madhuka will demonstrate a significant clinical benefit over Talishadi Churna in alleviating the symptoms of Tamaka Shwasa, thereby providing a potentially safer and cost-effective alternative in the management of bronchial asthma.
Keywords: Shwasa Roga, Bharangyadi Madhuka, Talishadi Churna, Tamaka Shwasa, bronchial asthma.

I. INTRODUCTION

Bronchial asthma (*Tamaka Shwasa* in Ayurvedic terminology) is a chronic respiratory disorder characterized by episodic breathlessness, wheezing, cough, and chest tightness. [4] With an increasing global prevalence, conventional therapies—although effective—are often linked to undesirable side effects (e.g., tremors, palpitations, hyperglycemia). [5] Ayurveda offers a holistic approach to managing such conditions, emphasizing the restoration of *doshic* balance and the use of natural remedies with minimal side effects. Classical Ayurvedic texts such as the *Charaka* and *Sushruta Samhitas* describe *Tamaka Shwasa* in detail, attributing the condition to the vitiation of *Prana Vayu* coupled with a *Kapha* imbalance. Globally, asthma is ranked 24th among the leading causes of years lived with disability and 34th among the leading causes of burden of disease, as measured by disability-adjusted life years (DALYs). According to the World Health Organization, between 100 and 150 million people worldwide suffer from bronchial asthma, Amongst India's 1.36 billion people, about 35 million suffer from asthma. [6] Previous studies have evaluated various formulations, yet there remains a lacuna in comparative research on *Bharangyadi Madhuka*—a formulation combining the effects of *Bharangi*, *Madhuka*, and *Haritki*—with the more traditionally established *Talishadi Churna*. This protocol article outlines a clinical investigation designed to bridge this research gap.

II. OBJECTIVES

A. *Primary Objective*

- To clinically evaluate and compare the efficacy of *Bharangyadi Madhuka* with *Talishadi Churna* in the management of *Tamaka Shwasa* (Bronchial Asthma).

B. *Secondary Objectives*

- To assess the impact of the interventions on biochemical markers and objective clinical parameters.
- To document the safety profile and adverse drug reactions associated with each treatment.
- To provide a standardized Ayurvedic treatment modality for *Tamaka Shwasa* that can be integrated with contemporary clinical practice.

III. METHODS

A. *Study Design*

This study is designed as an open-labelled, parallel comparative clinical trial. The trial will be conducted at the Institute for Ayurved Studies & Research, Faculty of Ayurved, Shri Krishna Ayush University, Kurukshetra.

B. Study Population

1) Inclusion Criteria

- Patients aged between 25 and 60 years.
- Clinical diagnosis of *Tamaka Shwasa* (Bronchial Asthma) according to classical Ayurvedic criteria and confirmed by modern criteria (NAEPP classification for mild intermittent or mild persistent asthma).
- Willingness to participate in the trial with documented written informed consent.

2) Exclusion Criteria

- Patients with significant systemic comorbidities (e.g., congestive heart failure, coronary artery disease, pulmonary hypertension, uncontrolled diabetes, chronic kidney disease, or autoimmune disorders).
- Pregnant or lactating women.
- Patients on corticosteroid therapy or those with secondary respiratory diseases.
- Any patient unwilling to undergo the clinical trial process.

C. Sample Size

A total of 60 patients will be enrolled, with 30 patients allocated to each treatment group.

D. Randomization and Allocation

Eligible patients will be randomly assigned to one of the two groups using a computer-generated randomization schedule.

E. Interventions

1) Group A: Bharangyadi Madhuka

- Preparation: A homogeneous mixture of equal parts of:
    - *Bharangi* (Clerodendrum serratum, root)
    - *Madhuka* (Glycyrrhiza glabra, root)
    - *Haritki* (Terminalia chebula, fruit)
- Administration: The prepared powder will be administered at a dose of 6 gm BD after meals, with vishammatra of madhusarpi (in a 2:1 ratio).

2) Group B: Talishadi Churna

- Preparation: A standardized mixture of:
    - *Talish* (Abies webbiana, leaf) – 1 part
    - *Marich* (Piper nigrum, fruit) – 2 parts
    - *Shunthi* (Zingiber officinale, dried rhizome) – 3 parts
    - *Pippali* (Piper longum, fruit/root) – 4 parts
    - *Vansh lochana* (Bambusa arundinaca, root/leaf/fruit) – 5 parts
    - *Ela* (Elettaria cardamomum, seed) – ½ part
    - *Tvak* (Cinnamomum zeylanicum, bark) – ½ part
    - *Sharkara* (Sugar) – 32 parts
- Administration: The mixture is administered at a dose of 6 gm BD after meals with honey.

F. Treatment Duration and Follow-up

- Treatment Phase: 21 days.
- Follow-up Schedule: Assessments on days 0 (baseline), 7, 14, and 21 during the treatment phase, followed by post-treatment evaluations on days 28, 35, and 42.

G. Outcome Measures

1) Primary Outcome

- Clinical Improvement: Assessed by a composite score comprising subjective parameters (frequency, duration, and intensity of dyspnea, cough, and other cardinal symptoms) and objective clinical findings (e.g., wheezing, rhonchi, and accessory muscle use).

2) Secondary Outcomes

1) Objective Assessments: Changes in laboratory parameters (including Hb, ESR, CRP, AEC) and pulmonary function tests (PFTs) where applicable.
2) Safety Assessment: Recording and evaluation of adverse drug reactions (ADR) throughout the study.
3) Overall Efficacy: Categorized using a predefined grading scale ranging from non-satisfactory (<25% improvement) to excellent (75–100% improvement).

IV. ASSESSMENT CRITERIA

A. Subjective Criteria [7]–

During the study, patients will be assessed on the basis of symptoms.

The following Symptoms (*Charaka Chikitsa.17 Hikkashwasa)[18]* were Assessed

1) Frequency of Shvasa Vega

No Attacks during the last 1 month	0
Frequency of Attack once a month	1
Frequency of Attacks once in two weeks	2
Frequency of Attacks once a week	3
Frequency of Attacks twice a week	4
Frequency of Attacks once or more than once a day.	5

2) Duration of Attack

No Episode of Attack -	0
Attack lasting for a Duration of 1/2 - 1 hr.	1
Attack lasting for a Duration of 1 - 6 hr	2
Attack lasting for a Duration of 6 - 12 hr	3
Attack lasting for a Duration of 12 hr	4
Attack lasting for a Duration of more than 12 hr	5

3) Intensity of Attack

Asymptomatic and normal lung function between exacerbations.	0
Intermittent Symptoms < once a week. Brief exacerbation (From a few hours to a few days), nighttime symptoms < 2 times a month.	1
Symptoms > once a week but < once per day, exacerbation affects activity & sleep, night time asthma symptoms > twice a month.	2
Symptoms daily exacerbations affecting activity and sleep, and nighttime a st h m a symptoms > 1 time a week.	3
Continuous Symptoms, frequent exacerbations, frequent nighttime asthma symptoms and physical activity limited by asthma symptoms.	4

4) *Presence of Pranavaha Sroto Dushti Lakshana*

Absent	0
Less than 25%	1
Between 25 - 50%	2
Between 50 - 75%	3
More than 75%	4

5) *Asino labhate Saukhyam:*

Relief in lying Position	0
Temporarily feels better in Sitting posture	1
Sitting Posture gives relief.	2
Spontaneous Sitting posture, can't sleep	3

6) *Shvasakrichhrata*

No sign of *Shvasakrichhrata*	0
Mild intercostal retraction, Nasal alae furring & can speak complete sentences during dyspnoea.	1
Intercostal retraction, Sternocleidomastoid muscle use & speaks in phrases or partial sentences during dyspnoea	2
Tracheo Sternal retraction, Intercostal retraction, sternocleidomastoid use & speaking in single words during dyspnoea.	3
Nasal alae furring & cannot able to speak during dyspnoea	4
All accessory muscles are working & not able to speak, expressed by body language.	5

7) *Kapha Nisthivanam*

No *Kaphanisthivanam*	0
Kaphanisthivanam only in the early morning	1
Kaphanisthivananam 2 - 3 times daily	2
Always *Kaphanisthivanam*	3

8) *Kasa*

No cough.	0
Cough dry without pain / wet with easy expectoration.	1
Dry cough with pain and expectoration with slight difficulty.	2
Dry cough with severe pain stabbing, cutting/feeling of restlessness because of difficulty expectoration.	3
Frequent coughing due to which the patient becomes unconscious / Fainting.	4

9) Kasatah Sannirudhyate

No such feeling	0
Occasional *Kasatah Sannirudhyate*	1
Very often *Kasatah Sannirudhyate*	2
Always *Kasatah Sannirudhyate*	3

10) Urahshula / Parshvashula

No *Urahshula*	0
Urahshula along with the attack	1
Very often *Urahshula* even without attack but relieved by local *Snehana & Swedana*	2
Very often *Urahshula* without attack & not relieved by local *Snehana & Swedana*	3
Always *Urahshula*	4

11) Kanthoddhvansanam (Irritation in Throat)

No *Kanthoddhvansanam*	0
Occasional *Kanthoddhvansanam*	1
Very often *Kanthoddhvansanam*	2
Always *Kanthoddhvansana*m	3

12) Shleshma Vimokshante Muhurtam Sukham

No such feeling	0
S.V.M. *Sukham* during attack	1
Very often S.V.M. *sukham*	2
Always S.V.M. *sukham*	3

13) Peenasa

No *Peenasa*	0
Peenasa during attack & subside 1-2 days after attack	1
Peenasa during the attack & persists for a week after the attack	2
Peenasa very often without attack	3
Peenasa always persisting	4

14) Ushnabhinandati:

No particular	0
Likes if available	1
Always prefer	2
Can't take cold things	3

15) Trit (Trishna) / Vishushkasyata

No *Trit / Vishushkasyata*	0
Occasional Trit / Vishushkasyata	1
Very often *Trit / Vishushkasyata*	2
Always *Trit / Vishushkasyata*	3

V. OBJECTIVE CRITERIA

1) Rhonchi

Absent on normal breathing but few rhonchi on forced breathing.	0
Few scattered bilateral rhonchi on normal deep breathing.	1
Rhonchi in between grades 1 & 3 on normal deep breathing.	2
Innumerable high-pitched bilateral rhonchi on normal deep breathing.	3

2) Wheezing

No wheezing	**0**
Wheezing only in the early morning; doesn't require any medicine	**1**
Wheezing in the early morning; requires medicine	**2**
Wheezing in the early morning & occasionally during the daytime.	**3**
Wheezing throughout the day & requires medicine	**4**
Wheezing throughout the day & not responding to any medicine, requires	**5**

A. Statistical Analysis

Data will be expressed as mean ± standard deviation. Intergroup comparisons will be performed using independent t-tests (or non-parametric equivalents if data distribution is non-normal) and paired t-tests will assess within-group changes. A p-value < 0.05 will be considered statistically significant. Standard statistical software will be used to analyze the data.

B. Ethical Considerations

1) Written informed consent will be obtained from all participants prior to enrollment.
2) The study protocol has received approval from the Institutional Ethics Committee of the Institute for Ayurved Studies & Research, Kurukshetra.
3) The trial is registered with the Central Trials Registry-India (CTRI).
4) Confidentiality of patient data will be strictly maintained.
5) Adverse events will be monitored and reported in accordance with regulatory guidelines.

VI. DISCUSSION

This study is designed to address the existing research gap in Ayurveda regarding the comparative efficacy of *Bharangyadi Madhuka* versus *Talishadi Churna* in managing *Tamaka Shwasa*. *Talisapatradi Churna* has *Kapha Lekhana* & *Kapha Vatahara* properties. It acts as an expectorant, which helped in reduction of *Shwasakruchrata*. Due to anti-inflammatory, it has bronchodilator and expectorant actions.

It can effectively drain out the mucus and reduce airway resistance. *Talisapatradi Churna* having *Katu Rasa, Laghu Ruksha Guna, Ushna Veerya* & *Kapha Vatahara* properties facilitates liquefaction of the mucus and thus helped in reduction of *Kasa* & *Kapha Nishteevana. Ushna Teekshna Katu* properties of drugs in *Talisapatradi Churna* helps in reduction in production of *Kapha* and increases elimination of *Kapha*. Thus clearing the airway obstruction and *Vata Anulomana* which in turn reduces the broncho constriction and dyspnea. The *Teeksha Guna, Ushna Veerya* & *Kapha Vata Shamaka* properties of *Talisadpatradi Churna* helped in reduction of cough, thereby relieved *Parshwashoola.* Due to *Ruksha Guna, Ushna Veerya* of *Talisapatradi Churna,*there was reduction in *Kapha* causing relief in symptom of *Muhurmuhur Shwasa. Bharangyadi Madhuka are Kaphaghan, Kasahar, and Shwashar* beneficial in *Pratishyaya, Kasa, Shwasa, and Yakshma. Bharangi* has *kaphavaatshamak* property due to its *Ushana virya. Acharya Charaka* described the *Dravya* of these properties as a line of treatment in *Tamaka Shwasa. Madhuka* has *Kaphanissarak and Kanthya* properties and contains The anti- inflammatory and expectorant activity of glycyrrhizic acid. *Rasayan* property of *Madhuka* also helps in boosting immunity. By integrating classical Ayurvedic principles with modern clinical evaluation methods, the study aims to provide robust evidence regarding the safety and effectiveness of these interventions. The open-label design, while a limitation, is mitigated by rigorous outcome assessments that include both subjective and objective measures. If *Bharangyadi Madhuka* demonstrates superior efficacy or safety over the comparator, this could pave the way for broader integration of Ayurvedic interventions in the management of bronchial asthma and contribute significantly to cost-effective and safe therapeutic strategies.

VII. CONCLUSION

This protocol outlines an open-labeled, parallel comparative clinical trial to assess the efficacy of *Bharangyadi Madhuka* versus *Talishadi Churna* in the management of *Tamaka Shwasa* (Bronchial Asthma). Through meticulous documentation of clinical and laboratory parameters over a defined follow-up period, this study intends to fill a crucial research gap and potentially validate a novel Ayurvedic treatment strategy that may benefit patients suffering from asthma. Future large-scale studies could further consolidate these findings and support the integration of effective Ayurvedic treatments into modern clinical practice.

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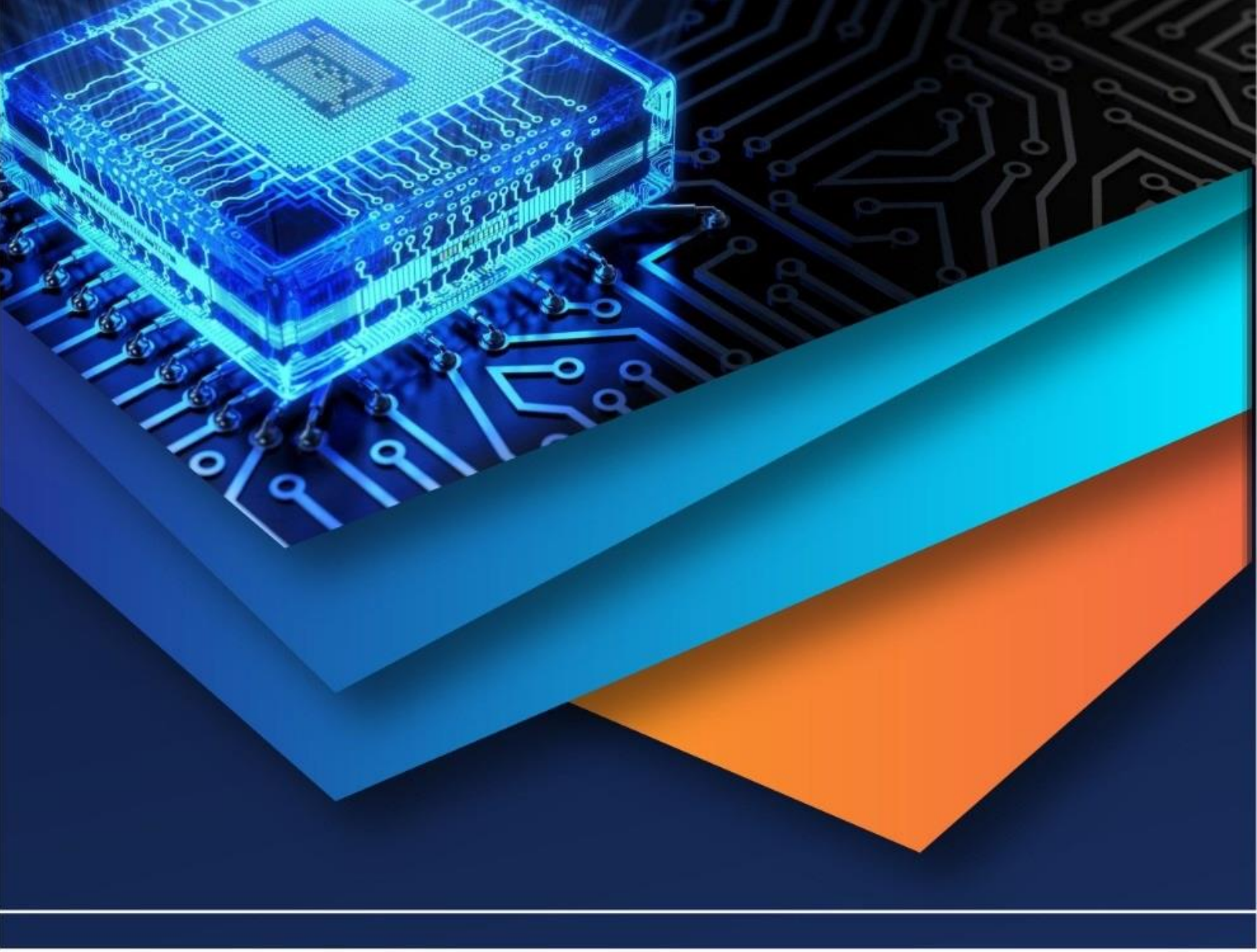

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