DOI: 10.7860/JCDR/2025/72718.20741

Research Protocol

Ayurveda Section

Determination of Optimal Dose of *Gandharva Taila Bhrushta Haritaki Churna* Ayurvedic Oral Preparation in the Management of *Krura Koshtha* (Severe Bowel Movements): A Randomised Clinical Trial Protocol

NITIN ASHOK DHAWAS[1], VAISHALI KUCHEWAR[2], MOHNISH GOKHALE[3]

ABSTRACT

Introduction: In Ayurveda, *Koshtha* is defined as a bowel movement based on an individual's basic constitution. There are three types of *Koshtha-Mrudu* (soft stool), *Madhyam* (moderate), and *Krura* (harsh or severe gastrointestinal nature). Individuals with Krura *Koshtha* are more prone to various diseases due to improper *Koshtha Shuddhi*. Hence, *Koshtha Shuddhi* (cleansing or purifying the gastrointestinal tract) is an integral part of treatment for most diseases. *Virechan* (therapeutic purgation or induced bowel evacuation) is advised for *Koshtha Shuddhi*.

Need of the Study: The action of *Anulomana Dravyas* (the drugs that gently stimulate downward movement in the intestines to facilitate bowel evacuation) affects the entire gastrointestinal tract. *Gandharva Taila Bhrushta Haritaki* is recognised as the best *Anulomaka*. The recommended dose of *Gandharva Taila Bhrushta Haritaki Churna* is described as 5-10 grams at night. Therefore, the present study is planned to confirm the optimal dose of *Gandharva Taila Bhrushta Haritaki Churna* for appropriate *Koshtha Shuddhi* in individuals with *Krura Koshtha*.

Aim: To determine the optimal dose of *Gandharva Taila Bhrushta Haritaki Churna* in the management of *Krura Koshtha* volunteers.

Materials and Methods: This is a three-armed parallel interventional trial, will be conducted in the *Kayachikitsa* Outpatient Department (OPD) and Inpatient Department (IPD), Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, from July 2024 to July 2025. A total of 90 participants who meet the inclusion criteria will be identified and randomly enrolled in three groups: Group A, Group B and Group C. *Gandharva Taila Bhrushta Haritaki Churna* will be administered orally to Groups A, B and C in doses of 5 grams, 7.5 grams and 10 grams, respectively, for seven days, once at bedtime. Daily follow-up will be conducted to assess *Koshtha Shuddhi*. Data will be analysed using the Chi-square test to find significant differences between the three groups concerning categorical variables of the Bristol stool chart, with a significance level set at p-value <0.05.

Keywords: *Anulomak*, Gastrointestinal tract, Therapeutic purgation, *Virechan*

INTRODUCTION

In Ayurveda, the term '*Koshtha*' has two meanings. According to anatomy, *Koshtha* refers to the hollow areas in the body that contain organs such as the stomach, liver, spleen, pancreas and intestines, as well as, the pelvic cavity, which includes the uterus, the lower part of the bowel and the urinary bladder. Based on an individual's basic constitution, *Koshtha* is defined physiologically as a bowel movement [1]. There are two kinds of therapeutic modalities: *Shodhan* and *Shaman*. *Shaman* is used to lessen the irritated *Doshas* already present in the body, while *Shodhan* is used to remove the aggravated *Doshas* from the body [2]. The evaluation of *Koshtha* is crucial to the patient's diagnosis and course of care. According to a person's basic constitution, *Koshtha* is described physiologically as a bowel movement. There are three types of *Koshtha*: *Mrudu Koshtha* (soft stool), *Madhyam Koshtha* (moderate) and *Krura Koshtha* (severe/hard). Persons with *Krura Koshtha* are more prone to diseases due to *Koshtha Shuddhi*; hence, *Koshtha Shuddhi* is an integral part of treatment for most diseases [3]. In Ayurveda, *Virechan* is advised for *Koshtha Shuddhi* [4]. Various types of *Virechan*, such as *Anulomana*, *Sramsana*, *Bhedana* and *Rechana*, are mentioned by *Sharngadhara* [5]. *Haritaki* (*Terminalia chebula*) is the most commonly used medicine for bowel cleansing. It is known as *Anulomak* (moderate laxative) [6]. *Gandharva Taila Bhrushta Haritaki*, a combination of *Haritaki Churna* and *Erand Tail*, is frequently used by Ayurveda practitioners. Therefore, the present study will be conducted to determine the optimal dose of *Gandharva Taila Bhrushta Haritaki Churna* in the management of *Krura Koshtha* in volunteers.

Primary objective: To determine the optimal dose of *Gandharva Taila Bhrushta Haritaki Churna* for achieving effective *Koshtha Shuddhi* (cleansing of the gastrointestinal tract) in volunteers presenting with *Krura Koshtha*.

Secondary objective: To evaluate the effect of *Gandharva Taila Bhrushta Haritaki Churna* on appetite by assessing Agni (digestive fire) in volunteers with *Krura Koshtha*.

REVIEW OF LITERATURE

The use of *Gandharva Taila Bhrushta Haritaki Churna* in the treatment of *Krura Koshtha* highlights its purgative properties and the role of taila (oil) in enhancing the effectiveness of *Haritaki*. In classical *Ayurvedic* texts, *Haritaki* is considered an *Anulomak* drug [7], as mentioned by *Acharya Charak* in *Sutrasthan*. In *Bhavprakash Madhya Khand*, the *Haritaki Varga* emphasises its synergistic effects in treating constipation [8]. Jirankalgikar YM et al., conducted a study comparing the intestinal transit time of two dosage forms of *Haritaki*. Both forms demonstrated significant intestinal motility-enhancing effects, indicating the mechanisms of *Anulomana* drugs described in Ayurveda. Among the forms, *Churna* showed a slightly stronger effect and is preferred over *Vati* for treating *Malavibandha* (constipation) [9].

Anumol K et al., conducted a systematic review on Eranda Taila (*Ricinus communis Linn.*). This review detailed its usage, dosage, adverse reactions and other properties. *Srotorodha* (obstruction of channels) is a major cause of disease, and Eranda Taila, being a conventional laxative, has fewer adverse effects and is inexpensive. It pacifies *Vata* and *Kapha doshas*, is *Sookshma* (subtle), *Srotoshodhana* (cleanses channels) and *Rasayana* (rejuvenation). *Eranda Taila's* therapeutic value is significant, and it can be used in various conditions [10].

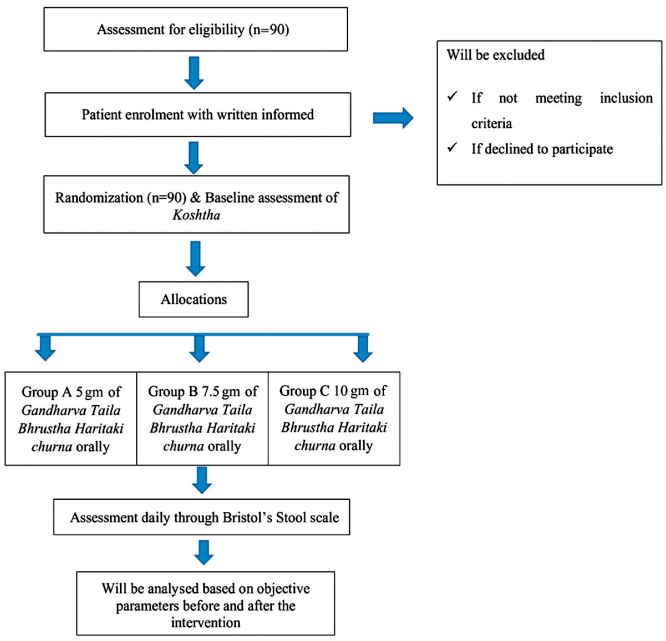
The action of *Anulomana dravyas* affects the entire gastrointestinal tract, and *Gandharva Taila Bhrushta Haritaki* is known as the best *Anulomak*. Therefore, the present study aims to determine the appropriate dose of *Gandharva Haritaki Churna* for *Koshtha Shuddhi* (bowel cleansing) in volunteers with *Krura Koshtha*.

MATERIALS AND METHODS

This study is a three-armed, parallel interventional trial that will be conducted in the *Kayachikitsa* OPD and IPD, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, along with peripheral camps, from July 2024 to July 2025. The study aimed at determining the optimal dose of *Gandharva Taila Bhrushta Haritaki Churna* in the management of *Krura Koshtha*. Ethical approval has been obtained from the Institutional Ethics Committee (IEC) of Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Wardha (Approval No.: MGACHRC/IEC/Jun-2024/815), and the study is registered under the Clinical Trials Registry of India (CTRI Registration No.: CTRI/2024/01/061096). Randomisation will be carried out using a computer-generated table method. Subjects will be recruited after obtaining written informed consent in their language, with all aspects of the study explained to them prior to commencement. Patient confidentiality will be maintained throughout the study.

Inclusion criteria: Patients who are willing to participate and provide written informed consent, those experiencing irregular stool passage, hard and dry stools, requiring straining or prolonged time for defecation, individuals needing daily purgatives, and patients with controlled Non Insulin-dependent Diabetes Mellitus (NIDDM) or hypertension along with hard bowel movements were included in the study.

Exclusion criteria: Pregnant or breastfeeding women, individuals with known gastrointestinal disorders, those with a predominance of *Pittaj Prakriti*, recent *Raktamokshan* (bloodletting therapy), and those who are fasting were excluded from the study. The selection of patients is explained in [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Sample size calculation: The sample size was calculated based on a mean difference of 0.64 for constipation, with a standard deviation of 0.75 [11]. Using the formula for mean difference, the sample size was determined to be 29 per group, adjusted to 30 per group (groups A, B, and C) to account for any dropouts.

Study Procedure

The primary variable is the difference in constipation scores, and the Chi-square test will be used to assess the significance of differences in categorical variables, such as outcomes measured by the Bristol stool scale, across the three groups. This test is appropriate as it evaluates relationships between categorical variables and is robust for data that may not meet normality assumptions.

Assessment tools:

Subjective parameters: Bristol's stool scale [12] is explained in [Table/Fig-2].

Type 1	Separate hard lumps, like nuts (hard to pass)
Type 2	Sausage-shaped but lumpy
Type 3	Like a sausage but with cracks on its surface
Type 4	Like a sausage or snake, smooth and soft
Type 5	Soft blobs with clear-cut edges (passed easily)
Type 6	Fluffy pieces with ragged edges, a mushy stool
Type 7	Watery, no solid pieces. Entirely Liquid

[Table/Fig-2]: Bristol's stool scale [12].

Preparation:

Step 1: Murchhit *Erand Tail* preparation [13]. 'Eranda Taila' will be placed in a container in its raw state. Heat over a small fire until foam develops; then, extinguish the flame and allow it to cool.

Step 2: To prepare *Gandharva Haritaki*, authentic *Haritaki* fruits are selected. These fruits are fried in processed *Murchhita Erand Taila* (castor oil). After frying, the *Haritaki* fruits are finely powdered and sifted through an 80-number sieve mesh. This process results in *Gandharva Haritaki Churna*, which is blended with *Murchhita Erand Taila*. Finally, the *churna* is packed into airtight containers to maintain its quality and efficacy.

The flow of interventions that will be conducted in the study is explained in [Table/Fig-3].

Group	Sample size	Intervention	Dose and frequency	*Anupana* (Adjuvant)	Duration	Follow-up
A	30	*Gandharva tailabhrustha haritaki churna*	5 gm at bedtime	Luke warm water	7 days	Daily
B	30	*Gandharva tailabhrustha haritaki churna*	7.5 gm at bedtime	Luke warm water	7 days	Daily
C	30	*Gandharva tailabhrustha haritaki churna*	10 gm at bedtime	Luke warm water	7 days	Daily

[Table/Fig-3]: Interventional table.

Criteria for discontinuing or modifying allocated interventions: Criteria for discontinuing or modifying allocated interventions: If an unforeseen event occurs, medication sensitivity manifests, or any other illness or issue arises, the subject will be removed from the study and provided with free therapy until the problem is resolved. To evaluate and track medication adherence, the authors will monitor the quantity of medication taken, and the patient will be observed during treatment.

The Gantt chart is presented in [Table/Fig-4].

Outcomes:

Primary outcomes: The primary outcome is the effectiveness of 5 g, 7.5 g and 10 g doses of *Gandharva Taila Bhrushta Haritaki Churna* on *Koshtha Shuddhi*.

Steps	Q1	Q2	Q3	Q4	Q5	Q6
IEC approval						
Drug collection						
Literature review						
Analytical study						
Bioavailability study						
Data analysis						
Writing the rest of the thesis submission						

[Table/Fig-4]: Gantt chart.

Secondary outcomes: The secondary outcomes include adverse effects, patient compliance, and the effect on appetite by assessing *Agni* (digestive fire) [14] through *Jaran Shakti* (digestive capacity) and *Abhyavaran Shakti* (intake capacity).

STATISTICAL ANALYSIS

Data will be analysed using statistical software R, with descriptive statistics summarising the data, and a p-value of less than 0.05 will be considered statistically significant.

REFERENCES

[1] Ragad SS, Gokhale MV. Ayurvedic concept of Koshtha and its importance in Panchkarma. Inter J Res Granthaalayah. 2019;7:416-21.
[2] Awasthi S, Gandharve S, Sood R, Sharma S. Conceptual study of Shodhana and Shamana Chikitsa. Int Res J Ayurveda Yoga. 2023;6(1):60-63.
[3] Sharma AR, editor. Susruta Samhita, Maharshi Susruta. Susrutavimarsini Hindi commentary. Varanasi: Chukhambha Prakashan; 2010. p. 427.
[4] Shukla V, Tripathi R, editors. Charaka Samhita. Vol. 1. 1st ed. Varanasi: Chaukhambha Surbharati Prakashan; 2007.p. 123-125.
[5] Sarngadhara. Sarngadhara Samhita. Purva Khanda, Chapter 4/2-7. In: Murthy KR, editor. Reprint edition. Varanasi: Chaukhamba Orientalia; 2012. p. 17.
[6] Gupta PC. Biological and pharmacological properties of Terminalia chebula Retz. (Haritaki)-An overview. Int J Pharm Pharm Sci. 2012;4(3):62-68.
[7] Shukla V and Tripathi R. Editors. Charak Samhita, Sutrathan, Chapter 13. Verse 10, Delhi: Choukhambha Sanskrit Pratisthan; 2012.p.198.
[8] Bhavamishra S. Bhavaprakasha Nighantu. Pandey GS, editor. Varanasi: Chaukhamba Bharati Academy; 2013. p.234-236.
[9] Jirankalgikar YM, Ashok BK, Dwivedi RR. A comparative evaluation of intestinal transit time of two dosage forms of Haritaki [Terminalia chebula Retz.]. Ayu. 2012;33(3):447.
[10] Anumol K, Krishna CM, Venkateshwarlu B, Sivaram G, Babu G. A comprehensive review on Eranda Taila (Ricinus communis Linn.). AYUSH. 2018:1384-89.
[11] Kumari M, Meena KL, Vardhan P. A randomized clinical study to compare the effect of Eranda Bhrishta Haritaka Churna orally and Trivrita Taila Matrabasti for Apana Vata Anulomana in Udavartini Yonivyapada (Primary Dysmenorrhea). JOA XIII-3; J Ayurveda. 2019;3:73-86.
[12] Heaton KW, Radvan J, Cripps H, Mountford RA, Braddon FE, Hughes AO. Defecation frequency and timing, and stool form in the general population: a prospective study. Gut. 1992;33(6):818-24.
[13] Katore AS, Wanjari A, Rathi B, Khan M, Sonare M. Pharmaceutical and analytical study of Gandharva Haritaki prepared by Murchhit and Amurchhit Erand tail and comparative assessment for in vitro bio-accessibility. Syst Rev Pharm. 2023;14(3):204-08.
[14] Patil VC, Baghel MS, Thakar AB. Assessment of Agni (digestive function) and Koshtha (bowel movement with special reference to Abhyantara snehana (internal oleation). Ancient Sci Life. 2008;28(2):26.

PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Scholar, Department of Kayachikitsa, Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India.
2. Professor, Department of Kayachikitsa, Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India.
3. Postgraduate Scholar, Department of Kayachikitsa, Datta Meghe Institute of Higher Education and Research Centre, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Nitin Ashok Dhawas,
Postgraduate Scholar, Room No. 30, Department of Kayachikitsa,
Datta Meghe Institute of Higher Education and Research Centre,
Wardha-442004, Maharashtra, India.
E-mail: nitindhawas31@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: May 09, 2024
- Manual Googling: Oct 08, 2024
- iThenticate Software: Oct 10, 2024 (8%)

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. NA

Date of Submission: **May 08, 2024**
Date of Peer Review: **Jun 27, 2024**
Date of Acceptance: **Oct 12, 2024**
Date of Publishing: **Mar 01, 2025**