Research Protocol

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Ayurveda Section

Efficacy of *Peganum harmala* Linn. Capsule versus *Trigonella foenum-graecum* Linn. Capsule in the Management of Primary Dysmenorrhoea: A Research Protocol

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ABSTRACT

Introduction: Primary dysmenorrhoea, also known as *Kashtartava* in Ayurveda, refers to painful menstruation that significantly affects the quality of life for many women, characterised by intense cramping and associated symptoms like headache, nausea, and back pain. Ayurveda, a holistic medical system, offers several herbal treatments for *Kashtartava*, among these, *Peganum harmala* Linn. seeds are recognised for their analgesic, antispasmodic, and anti-inflammatory properties. Similarly, *Trigonella foenum-graecum (Methi) seeds, traditionally used for various gynaecological conditions, show potential for pain relief in* management of *kashtartava.*

Need of the study: *Harmal (Peganum harmala* L.) has been traditionally used as a remedy in Ayurveda, but there has been limited scientific research on its medicinal properties, especially in treating primary dysmenorrhoea and painful menstrual periods. This research project will investigate the potential of *Harmal* seeds in addressing primary dysmenorrhoea (*Kashtartava*).

Aim: To evaluate the efficacy of *Harmal* (*Peganum harmala* Linn.) capsule versus *Methi* (*Trigonella foenum-graecum* Linn.) capsule in the management of primary dysmenorrhoea (*Kashtartava*).

Materials and Methods: A double-blind randomised controlled parallel design clinical trial will be conducted from June 2025 to September 2026. The patients will be recruited from the Outpatient Department (OPD) (*Prasuti Tantra avam Striroga* OPD) of Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India. Sixty patients will be randomised into two groups (each group contains 30). In Group A, *Peganum harmala* L. (*harmal seeds*) powder capsule 500mg BD, before a meal with water, will be given for three days, and Group B will be given *Trigonella foecum-graceum* (*Methi seeds)* powder capsule 2 gm BD, before a meal with warm water will be provided for three days. Regular follow-ups will be done on the 1st and 3rd day for three months at consecutive cycles. The Chi-squared test will be used to compare baseline characteristics between the two groups. A paired t-test or Wilcoxon signed-rank test will be used to assess the reduction in pain within each group from baseline to post-treatment. An unpaired t-test or Mann-Whitney U test will be used to compare post-treatment pain reduction between the two groups. A p-value<0.05 will be considered statistically significant.

Keywords: Analgesic, Menstrual pain, Pain management

INTRODUCTION

Ayurveda is a way to understand and treat life's health. It aims to cure and prevent diseases using different principles. Diseases have various causes, and factors like Dosha and Dushya contribute to their formation. In gynaecology, *Kashtartava* is a common disorder. It occurs when there's an imbalance in Vata, Kapha, and Pitta, which are elements in the body according to Ayurveda. *Kashtartava* in Ayurveda is comparable to dysmenorrhoea in modern science [1]. Dysmenorrhoea, denoting the distressing experience of painful menstruation, stands out as a prevalent gynaecological concern among women of reproductive age. A more practical definition encompasses cases where menstrual pain reaches a degree significant enough to hinder day-to-day activities [2]. Dysmenorrhoea prevalence rates range from 16 to 91%, with severe pain observed in 2 to 29% of women [3]. Another study estimated prevalence rates between 45% and 93% [4]. In India, recent findings highlight significant [5,6] regional and population-based variations in the prevalence of primary dysmenorrhoea. These findings underscore the need for comprehensive and standardised studies to better understand and address the prevalence of primary dysmenorrhoea in diverse regions of India. Dysmenorrhoea is a frequent concern among young women seeking medical help nowadays. Lifestyle changes, poor eating habits, and stress are significant factors contributing to dysmenorrhoea. In today's high-tech world, where women are equally involved in education and work, they can't afford to miss their responsibilities during each menstrual cycle. Additionally, women now have a lower tolerance for pain, which contributes to the higher reported cases of dysmenorrhoea.

In Ayurvedic classics, all gynaecological problems are described under the broad caption of *Yonivyapada* [7]. Though the disease "*Kashtartava*" is not defined in classics as an individual entity, it is a symptom of various *yonivyapadas,* especially *Udavarta*, *Vatala*, *Sannipatika* [8]. *Acharya Chakrapani* quoted that any symptom may manifest as an individual disease [9]. *Kashtartava* is a health issue in 15 to 50-year-old. It's a *vyadhi* related to *tridoshaja*, with *Vata* being the dominant factor in the female genital tract.

Analgesics and NSAIDS, which are active inhibitors of Prostaglandins (PGs) synthesis, are used to combat pain during Dysmenorrhoea, but these drugs produce side-effects on long-term use [10]. So, it's essential to find a safe and helpful solution to this problem nowadays. It's known that Ayurvedic medicine has been helpful for global healthcare, including managing dysmenorrhoea. People are now paying more attention to studying plants worldwide, exploring their potential benefits and uses. Ayurvedic management emphasises the use of herbal remedies like *Harmal* seeds for their analgesic [11], antispasmodic, and anti-inflammatory properties [12], and *Trigonella foenum-graecum* (*Methi*) seeds, traditionally used for gynaecological conditions, offering effective pain relief [13].

A review of ayurvedic texts and work done by other scientists suggests that herbs like *Shatapushpa* [14], *Methika* [15], *Satapa* [15], *Harmal* can be used in the management of *Kashtartava*. Amongst these herbs, *Harmal*, despite having a potential and textual reference in *Bhav Prakash Nighantu* for its use in *Kashtartava* [16], is yet to be screened.

REVIEW OF LITERATURE

The term '*Kashtaratava*' in Ayurveda denotes a condition where menstruation (*Artava*) is associated with pain. It is classified as a *Vata* and *Kapha* predominant disorder, with *Vata* being the primary dosha involved. The pathogenesis involves vitiated *Kapha* obstructing the *srotas* (channels), resulting in the abnormal upward movement (*pratiloma gati*) of *Apana Vayu*, ultimately causing painful menstruation (*rajakrichrita*) [17].

Peganum harmala, commonly known as Syrian rue or *Harmal*, is a perennial shrub belonging to the Zygophyllaceae family. Research by Shoaib M et al., (2016) showed crude alkaloid extracts of *P. harmala* to be effective in reducing pain via peripheral and central mechanisms [18]. A study by Aqel M and Hadidi M demonstrated that *Harmal* seed extract has a direct relaxant effect on smooth muscles in animal models, suggesting antispasmodic properties [19], while clinical trials conducted by Shirani-Boroujeni M et al., (2017) [20] and Shakeri N et al., (2020) validated its efficacy in reducing pain and urinary symptoms [21]. *Trigonella foenum-graecum*, or *Methi* is *Vatashamaka* and *Kaphanashaka*, traditionally indicated in conditions like *Vatik vikara*, *shoola* (pain), and *agnimandya* (loss of digestive fire). Modern phytochemical studies (Sastry, 2010) have identified key constituents like steroidal saponins- diosgenin and gitogenin- and alkaloids with anti-inflammatory and analgesic properties [22]. Moloudizargari M et al., (2013) confirmed Methi's anti-inflammatory potential in comparison with other herbs [23]. Both *Harmal* and *Methi* are described in Ayurvedic texts as *ushna virya* and *vedanahara*, suitable for alleviating *Vata*-related pain. The present study aims to examine the potential effects of *Harmal*, an herb known for its beta-carboline alkaloids and traditional use in relieving pain and muscle spasms. Although *Harmal* has been widely used in traditional medicine, it has not been clinically studied specifically for treating menstrual pain (dysmenorrhoea). Therefore, this research is being conducted to compare the Efficacy of *Harmal* (*Peganum harmala* Linn.) seed capsule versus *Methi (Trigonella foenum-graecum* Linn.) seed capsule in the management of Primary dysmenorrhoea (*Kashtartava*).

Primary objective:

- To assess the efficacy of *Harmal* seeds capsule on primary dysmenorrhoea (*Kashtartava*).
- To assess the efficacy of *Methi* seeds capsule on primary dysmenorrhoea (*Kashtartava*).
- To compare the efficacy of *Harmal* seeds *churna* capsule versus plant *Methi* seeds *churna* capsule on *Kashtartava* (primary dysmenorrhoea).

Secondary objective:

- To study pharmacognostical, physicochemical, and phyto-chemical characteristics of *Harmal* seed.
- To study pharmacognostical, physicochemical, and phyto-chemical characteristics of *Methi* seed.

Null Hypothesis (H0): Harmal (Peganum harmala L.) seeds are not as efficacious as Methi (Trigonella foenum-graecum L.) in Primary Dysmenorrhoea (*Kashtartava*).

Alternate Hypothesis (H1): Harmal (Peganum harmala L.) seeds are more efficacious than Methi (Trigonella foenum-graecum L.) in Primary Dysmenorrhoea (*Kashtartava*).

MATERIALS AND METHODS

A double-blind, randomised controlled parallel design clinical trial will be conducted at the Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, from June 2025 to September 2026. A Computer-generated random number table will allocate a patient. Informed consent will be obtained from each participant and participants under 18 years of age from their parents/guardians before enrolment in the study. Ethical clearance has been obtained from the IEC, and the registered IEC number is MGACHRC/IEC/Jun-2024/834. The trial has been registered on the CTRI website with the reference number (CTRI/2024/07/071499).

Study Procedure

A total of 60 patients with primary dysmenorrhoea (*Kashtartava*) will be recruited from the OPD and Inpatient Department (IPD) of the Department of Prasuti *Tantra avum Striroga* and through special camps in nearby localities. Patients will be randomised into two groups (30 patients each) using a computer-generated random number table. Group A (Intervention) will receive *Harmal* (*Peganum harmala* Linn.) seed *churna* capsules (500 mg, 1 capsule BD before meals with water) for 3 days per menstrual cycle. Group B (Control) will receive *Methi* (*Trigonella foenum-graecum* Linn.) seed *churna* capsules (2 gm BD before meals with warm water) for three days per menstrual cycle. The trial will be of three consecutive menstrual cycles, with follow-ups on the 1st and 3rd days of each cycle. Pain intensity and associated symptoms (e.g., nausea, headache, backache) will be assessed using the Visual Analogue Scale (VAS), and adverse events will be monitored and reported to the ethics committee.

Inclusion criteria:

- Unmarried women between the ages of 16 and 30 years;
- Patient willing to participate with written informed consent;
- Female patients who have experienced pain during their periods for more than two months in a row.

Exclusion criteria:

- Women less than 16 years and above 30 years;
- Women with any pelvic pathology and irregular periods;
- Patients with a history of other health problems that might affect the treatment process.

Withdrawal criteria:

- Patients are following the treatment irregularly.
- Patients absent following three follow-ups.

Sample size calculation: Sample size calculation for comparing two proportions based on % of reduction in pain:

$$n=\{(Z_{(1-\alpha/2)}\times\sqrt{((r+1)\times p(1-p))}+Z_{(1-\beta)}\times\sqrt{(p1(1-p1)+r\times p2(1-p2))})^2\} / \{r\times(p2-p1)^2\}$$

Where:

$p=(p1+r\times p2)/(1+r)$

r=Ratio of Group 2 to Group 1

Parameters:

- Alpha (α): 0.05
- Beta (β): 0.20
- Proportion in a reduction in pain Group 1 Hulba (*Trigonella foenum graceum* Linn) (p1)=0.6513 [24].

Considering a 30% pain reduction.

-Proportion in a reduction in pain Group 1 *Harmal* (p2)0.9513.

-Ratio (Group 2/Group 1): 1.

-Minimum sample size needed for Group 1: 27.

-Minimum sample size needed for Group 2: 27.

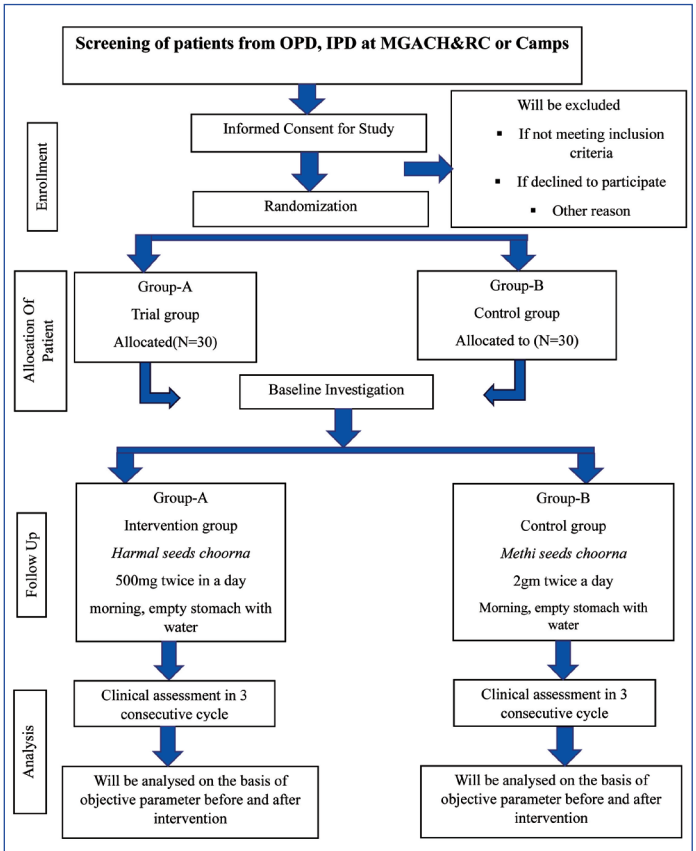
-Minimum total sample size: 54

Considering a 10% dropout rate, the total is six. The total sample size will be 60, i.e., 30 per group.

The study involved two groups, each consisting of 30 participants. *Harmal seeds churna* in capsule form, and *Methi seed churna* capsules will be administered twice daily before meals, with water for three days [Table/Fig-1,2] [20,25].

Group	Sample size	Intervention	Dose and frequency	Medium (Anupan)	Duration	Follow-up
A	30	*Harmal* seeds *churna* capsule (Intervention)	1Cap.500 mg (0.5gm) BD before meal [21]	water	3 days	1st day 3rd day
B	30	*Methi* seeds *churna* capsule (Standard Control)	4Cap.500 mg (2gm) BD before meal [26]	water	3 days	1st day 3rd day

[Table/Fig-1]: Two groups and their specific intervention with dose and duration.



[Table/Fig-2]: CONSORT chart.

Drug Analysis

Drugs will be collected from their natural habitat following good collection practices (WHO). Drug authentication will be done with the help of FRLHT Bangalore or the BSI office or the Botany department, or the Pharmacognosy department. of a reputed university or the Dravyaguna department of Ayurveda College. The authentication of the plant will be done by a well-known botanist at the Research Institute, who will be authenticated by sending a specimen voucher to the FLRHT Bangalore lab, the BSI or the Botany department. of or from the authorised person of the Dravyaguna department.

Drug Preparation

***Peganum harmala* (*harmala*) powder capsule preparation:** To prepare *Peganum harmala* (*harmal*) seed powder capsules, the plant seeds are first carefully collected. These seeds are thoroughly cleaned to remove any impurities and ensure purity. Once cleaned, the seeds are crushed into a fine powder and mixed well to achieve uniform consistency. This prepared seed powder is then encapsulated to create harmala seed capsules, ready for use [26].

***Methi* (*Trigonella foenum-graecum* Linn.) powder capsule preparation:** To prepare *Methi* (*Trigonella foenum-graecum* Linn.) seed powder capsules, plant seeds are carefully collected and thoroughly cleaned to remove any impurities. The cleaned seeds are then crushed into a fine powder and mixed well to ensure uniformity. This prepared powder is encapsulated, resulting in *Methi* seed powder capsules ready for use [27]. The study methodology steps have been presented in [Table/Fig-3].

Scholar/Investigator	Dr. Aditi Padoley					
Title	Comparative evaluation of efficacy of *Harmal (Peganum harmala* Linn.) capsule versus *Methi (Trigonella foenum-graecum* Linn.) capsule in the management of Primary dysmenorrhoea *(Kashtartava)*; A randomised control trial					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Approval from IEC						
Drug authentication and collection						
Drug Preparation						
Enrolment of the patients						
Data collection						
Statistical analysis						
Thesis writing						
Submission						

[Table/Fig-3]: Gantt chart showing study methodology and timeline.

Outcomes

Reduction in pain intensity will be evaluated by VAS Analogue scale [28] and which will be assessed at the 1st day, 3rd day for three menstrual cycles, and improvement in associated symptoms like anorexia, giddiness, burning, hot flushes, loose motion, backache and breast tenderness.

STATISTICAL ANALYSIS

The data will be analysed using Statistical Package for Social Sciences (SPSS) version 7.0 software. Baseline characteristics of participants between the two groups will be compared using the Chi-square test (for categorical variables) and independent (unpaired) t-test or Mann-Whitney U test (for continuous variables). Within-group comparisons of reduction in pain scores (pre- and post-treatment) will be analysed using the paired t-test or Wilcoxon signed-rank test. Between-group comparisons of post-treatment outcomes will be assessed using the independent (unpaired) t-test or Mann-Whitney U test. A p-value of less than 0.05 ($p<0.05$) will be considered statistically significant.

Guidelines: (Standard Protocol Items: Recommendations for Interventional Trials) guidelines are being used for the study

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