



**STUDY PROTOCOL OF RANDOMIZED OPEN CLINICAL TRIAL OF KANYALOHADI
VATI AND KUBERAKSHA VATI IN KASHTARTAVA**

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ABSTRACT

Background: Dysmenorrhoea or painful menses is a common gynecological problem adversely affecting the academic, professional performance and overall wellbeing of millions of women and adolescent girls worldwide. Due to the side effects of over-the-counter drugs being used, there is a need to find a therapeutic option for dysmenorrhoea which is safe, natural and effective. **Objective:** This clinical study is designed to evaluate the comparative efficacy of Kanyalohadi Vati and Kuberaksha Vati in patients with dysmenorrhoea. **Materials and Method:** This prospective, open-label, randomized trial will be conducted at Faculty of Ayurveda, Main Campus, Uttarakhand Ayurved University, Harrawala. A total of 100 participants will be enrolled in the study. Patients between 16-35 years of age, having dysmenorrhea for more than 3 cycles but no pelvic pathology, having scanty or normal menstrual flow, using analgesics and having Hb levels > 7gm% will be enrolled in the study. The enrolled patients will be randomly divided into two groups. Patients of Group A and Group B will be administered Kanyalohadi Vati and Kuberaksha Vati 2 tablets(500gms) with luke warm water after meals twice a day respectively. The therapy will commence 7days before expected menses and will continue 3 days during menses, consecutively for 3 menstrual cycles. The outcome measures are the changes in chief and associated symptoms of dysmenorrhoea. Patients will be assessed for graded subjective parameters of the same after each menses. **Discussion:** Ayurveda has been successfully managing dysmenorrhoea with oral drugs and Panchkarma therapies. Research works have been conducted on the efficacy of the trial drugs on dysmenorrhea but a comparative study has not been done. So, it is expected that the results of this trial may suggest a probable condition in which either of the two drugs may offer a better therapeutic option for the effective management of dysmenorrhoea.

KEYWORDS: Kanyalohadi Vati, Kuberaksha Vati, Kashtartava, Dysmenorrhoea, Menstrual disorders.

INTRODUCTION

Dysmenorrhea is formally recognized in the International Classification of Diseases (ICD-10-CM) under the category of genitourinary system disorders. This inclusion ensures standardized diagnosis, clinical documentation and reimbursement worldwide.^[1] Dysmenorrhea or painful menstruation is characterized by spasmodic uterine contractions or pain associated with inflammatory disturbances in the reproductive organs.^[2] Dysmenorrhea is a significant health concern, impacting women's quality of life, work productivity and healthcare utilization.

Studies from India reported that prevalence range between 50 to 87.8%.^[3] In a study conducted in Dehradun, Uttarakhand, India a significant percentage of adolescent girls reported experiencing dysmenorrhea, with 65% of the surveyed population reporting the condition.^[4]

A school-based study in Dehradun found that 51.56% of urban girls and 31.33% of rural girls remained absent from school during menstruation.^[5]

This condition can closely be related to *kashtartava* in Ayurvedic parlance. *Kashten munchayati artavam iti*

kashtartava i.e. when the shedding of *artava* or menstrual blood is accompanied with difficulty or pain.^[6] *Kashtartava* has been described as a symptom in various *Yonivyapad*^[7], *Artavadushiti*^[8] & *Artava kshaya*.^[9] As it has been very clearly stated by Acharya Charak that none of the gynecological disorders can arise without the vitiation of *Vata*^[10] and more specifically *Apana Vayu* is responsible for the proper and timely expulsion of *Shukra*, *Artava*, *Shakrit*, *Mutra* or *Garbha*.^[11] So, *Anulomana* of *Apana Vayu* is essential to treat *Kashtartava*.

The pain is significant in 15-20% women who report severe dysmenorrhea or pain that prevents them from participating in their day-to-day activities. In modern medicine, it is treated by oral contraceptive pills, nonsteroidal anti-inflammatory drugs, anti-spasmodics, analgesics etc^[14], prolonged use of which can cause side effects like hepatotoxicity, headache, dizziness, vertigo, depression, skin rashes etc. Due to limitation of medical therapy, it is the need of the hour to find out a safer, easier and effective natural ayurvedic regime which can be easily accepted by the patients. Ayurvedic treatment through *panchkarma* therapies and the use of oral medications are found effective in routine clinical practice and published research studies. As the target population is mainly school going or working females, it becomes difficult to arrange a week-long leave for treatment through *panchkarma* and so, oral medications seem more acceptable. *Kanyalohadi Vati* has been mentioned in *Rasa Sara Tantra Sara Va Siddha Prayoga Sangraha* in the *Gutika Prakarana* as being effective in painful, irregular menses and other gynecological disorders.^[15] *Kuberaksha Vati* has been described in *Bharat Bhaishajya Ratnakar* under *Shoola prakarana* and has been stated as being effective in *Astavidha Shoola* (all the eight types of pains mentioned in ayurvedic texts.^[16]

OBJECTIVE

This study is designed to compare the clinical efficacy of *Kanyalohadi Vati* and *Kuberaksha Vati* in *Kashtartava*.

MATERIALS AND METHOD

Study design and setting: This study is a prospective, open-label, randomized clinical trial. It is being conducted at Main Campus Hospital, Uttarakhand

Ayurved University, Harrawala, Dehradun, Uttarakhand, India.

Study participants

Inclusion criteria

Female patients between 16 to 35 years of age suffering from painful menses for more than 3 consecutive cycles, having scanty or normal menstrual flow will be included in the study.

Exclusion criteria

Patients having organic pathology of uterus, carcinoma of endometrium, PID etc or suffering from systemic chronic illness, having excessive bleeding during menses and whose hemoglobin level is less than 7gm/dl will be excluded from the study.

Study intervention

The enrolled participants in both the groups will be given 2 tablets of trial drugs (Group A-*Kanyalohadi Vati*, Group B- *Kuberaksha Vati*) twice a day with lukewarm water before meals, commencing 7 days before menses and 3 days during menses for 3 consecutive menstrual cycles.

Participants will be asked to come for follow-up at the cessation of first, second, third and fourth menses. Both the trial interventions are manufactured by a GMP-certified pharmacy, Nagarjun Pharmaceuticals, Dehradun, Uttarakhand, India. Both the drugs have been analyzed for organoleptic evaluation, physicochemical parameters, microbial contamination and pathogens before clinical trial.

Outcome Measures

Assessment will be done on the basis of scoring pattern for chief symptoms and associated symptoms before & after the treatment schedule.

Participants will be assessed for graded subjective parameters [Table 1] on each follow-up visit.

The primary outcome measure is the change in intensity and duration of pain during menstruation which will be assessed at baseline and at cessation of first, second and third menses. The schedule of enrollment, intervention, assessment, and follow-up visits for the study participants is given in Table 2.

Grading of chief and associated complaints

Symptom	Grade 0	Grade 1	Grade 2	Grade 3
Severity of pain	No pain, daily activity unaffected	Menses painful, daily activity not affected. No analgesics required	Menses painful, daily activity affected, analgesics required	Menses painful, normal routine activity affected, absent from class/office during menses, analgesics required but poor effect.
Duration	No pain in menses	Pain persists less than 12 hours	Pain continues for 12 – 24 hours	Pain continues for more than 24 hours
<i>Artava Pramana</i>	6–7 pads/day	4–5 pads/day	2-3 pads/day	Spotting or 1 pad/day
<i>Artavasrava Avadhi</i>	Duration of	Duration of menses 3	Duration of menses 2	Duration of menses 1

	menses 4-7 days	days	days	day
<i>Yathochitkala Adarshanam</i>	25-35 days	36-45 days	5Days	>55 days
<i>Praseka</i> (Nausea)	No Praseka	2-3 times/day	4-5 times/day	>5 times/day
<i>Chhardi</i> (Vomiting)	No Chhardi	Occasionally	1-2times/day	More than 2 times a day
<i>Vibandha</i> (Constipation)	No Vibandha	Frequency once a day but hard stool	Frequency of stool alternate day and difficulty in defecation	Patient cannot pass stool without any purgative even after 3-4days
<i>Atisara</i> (Diarrhoea)	No Atisara	Occasionally	2-3 times/day and drava mala pravritti	More than 3 times/day drava mala pravritti
<i>Shrama</i> (Fatigue)	No Shrama	Fatigue by single extra work other than daily routine	Fatigue by normal daily work	Severe fatigue even without work
<i>Aruchi</i> (Loss of appetite)	Takes full diet and proper appetite at next meal hour	Moderate appetite and prompt appearance of appetite in next meal hour	Low appetite but delayed appearance of appetite in next meal hour	Persisitentor frequent low appetite and unable to consume even low diet

Study Schedule

Study event	Screening	Baseline	After cessation of 1 st menses	After cessation of 2 nd menses	After cessation of 3 rd menses
Written informed consent	√				
Screening	√				
Laboratory investigations(CBC)	√				√
Laboratory investigation(Urine-Routine & micro)	√				√
Radiological investigation(Ultrasound) if needed	√				
Demographics & medical history		√			
Clinical assessment		√	√	√	√
Oral administration of drug		√ 7days before menses and 3 days during menses for 3 consecutive cycles			
Rescue medication			√	√	√
Assessment of adverse events			√	√	√

Withdrawal criteria: A study participant who develops any intolerable side effect or adverse drug reaction during the study period will be withdrawn from the study. Such patients will be given appropriate medical care or referred to a higher medical facility. Participants who are not willing to continue in the study or showing less than 80% compliance with the trial therapeutic regimen will also be withdrawn from the study.

Sample size

Sample size has been calculated using G power software. As the test being run is mean based, 2 tailed trial, effect size is medium, the desired level of power is 80% and alpha level is 0.05, the sample size required came out to be 128. But due to time, budget and other resource limitations, only 100 patients, 50 in each group will be enrolled in the study.

Randomization: The participants will be assigned to groups randomly by lottery system. The randomized

allocation of the participants in the two study groups will be concealed using sequentially numbered, opaque, and sealed envelopes.

Recruitment: After obtaining written informed consent from patients, eligible subjects with *Kashtartava* (Dysmenorrhoea) will be screened for eligibility to participate in the study. The participants will be enrolled from the outpatient department of Prasuti Tantra and Stri Roga, Main Campus Hospital, Uttarakhand Ayurved University, Harrawala, Dehradun, Uttarakhand, India, based on the predefined inclusion and exclusion criteria.

Ethical consideration: The study is approved by the Institutional Ethics Committee of the Uttarakhand Ayurved University, Gurukul Campus, Haridwar. Written informed consent will be obtained from the eligible patients by the investigator before enrollment. ICMR National Ethical Guidelines for Biomedical and Health

Research on Human Participants (2017) will be followed to execute the study.

Concomitant and rescue medication: Study participants will be enquired about concomitant medication for any unrelated ailment, and if any information will be there, the same will be recorded in the case record form (CRF). If there is a need for any rescue medication, it will be prescribed and noted in the CRF.

Compliance: Compliance will be assessed by the quantity of trial medication consumed during the intervention period. The same is evaluated through the compliance assessment form issued to the study participants. The participants' compliance should be more than or equal to 80%.

Data collection and documentation: Data of the enrolled participants will be collected at baseline and at cessation of first, second and third menses. The same will be recorded in the predesigned CRF. An attempt will be made to collect the outcome data from the participants who discontinue from the study through intermittent follow-up if the participant will be willing for the same.

Deviation from the protocol: Any deviation from the study protocol will be implemented in the study only after the approval from the IEC.

Confidentiality: All the information and records of the study participants will be kept confidential and their name and identity will not be disclosed.

Monitoring: As this study is a PhD research work, it will be monitored by the concerned supervisor and co-supervisor where this study will be conducted.

Statistical analysis

Statistical evaluation of the results will be done by using z test. Whereas subjective data will be assessed with Wilcoxon signed-rank test. Comparison of the effect of both the drugs will be done using Mann-Whitney test.

DISCUSSION

Kanyalohadi Vati has been described in *Rasa Tantra Sara va Siddha Prayoga Sangraha* in the *Gutika Prakarana*. It has been considered as being effective in painful menses, irregular menses and other gynecological disorders. The formulation contains *Elua*, *Kasisa*, *Dalchini*, *Ela*, *Shunthi* and *Gulkand*.

The main ingredients of the drug are *Lata Karanja*, *Shunthi*, *Sauvarchala Lavana*, *Hingu* and *Lashuna*. The medicine has been stated as being effective in all the eight types of pain (*Ashtavidha Shoola*) mentioned in ayurvedic texts.

The comparative clinical efficacy of the trial drugs will be discussed in light of the obtained result on the basis of Ayurvedic concept and modern scientific parameters.

Access to data: As the study is a PhD research work, the concerned supervisor and co-supervisor will have access to the final study data.

Ancillary and post-trial care: No ancillary studies are proposed with this trial. The participants will be provided routine medical care after the completion of the study period if required.

Dissemination: The outcomes of this study will be disseminated through original article in a peer-reviewed medical/Ayush journal and presentations at national conferences.

CTRI registration: The study is registered prospectively with the Clinical Trial Registry of India (CTRI/2022/07/044074).

Trial status: Recruitment of the patients has been done for this study. The clinical trial has been completed for both the groups.

Protocol number: UAU-PHD-PTSR-KST-01.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

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