Research Protocol

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Ayurveda Section

Evaluation of Comparative Efficacy of *Shatyadi Yoga* versus Dicyclomine Syrup in Management of *Udarshula* (Abdominal Pain) in Children: A Research Protocol

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ABSTRACT

Introduction: *Udarshula* is the most common complaint among infants and children due to dependency on others for food. Population-based research indicates that chronic abdominal pain affects 10-12% of school-aged children and nearly 20% of middle and high school students. *Vata Anuloman* is a term used in *Ayurveda* to describe a treatment that helps to normalise *Vata dosha* and clear the obstruction of the pathway of *Vayu*, which can cause abdominal pain. *Shatyadi yoga* mentioned in *Kashyap Samhita visheshkalpadhyay,* has *shula prashamana* as well as *deepana, pachana* property.

Need of the study: *Shatyadi Yoga*, a classical Ayurvedic formulation, offers a potentially safer alternative but lacks comparative clinical evidence. This study proposes to evaluate both treatments effectiveness and support integrative, evidence-based paediatric care. It addresses the need for safer, effective options and bridges gaps in Ayurvedic research.

Aim: To evaluate the comparative efficacy of Shatyadi Yoga versus dicyclomine syrup in the management of Udarshula (abdominal pain) in children.

Materials and Methods: This double-blind superiority clinical trial will be conducted from February 2025 to January 2026, at Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (H) Wardha. A total of 60 patients who meet the inclusion criteria will be randomly assigned to two groups. Group 1 will receive *Shatyadi yoga*, while Group 2 will receive dicyclomine syrup, administered twice daily for 14 days. Assessments will be conducted on day 0, day 3, and day 7, with follow-ups on days 14 and 28. Outcomes will be measured using the Faces Pain Scale-Revised (FPS-R) and a self-reported assessment of pain severity from the International Association for the Study of Pain (IASP), along with a parental questionnaire. Statistical analysis will be performed using the paired t-test and unpaired t-test, and a p-value of less than 0.05 will be considered statistically significant.

Keywords: Ayurveda, Colic, Digestive system disease, Faces pain scale-revised, Paediatrics, Pain measurement

INTRODUCTION

Udarshula, or abdominal pain, is a prevalent complaint among infants and children, often arising from their reliance on caregivers for nourishment. Many children consume external foods, packaged snacks, and bakery items in excess, frequently lacking awareness of the potential health impacts. These types of food can be cumbersome to digest and may result in gastrointestinal disturbances [1]. *Vata Anuloman* is a specific Ayurvedic treatment designed to normalise *Vata dosha* and alleviate obstructions in the pathway of *Vayu*, which may lead to abdominal discomfort [2]. The efficacy of *Vata Anuloman* lies in its ability to balance an aggravated *Vata dosha*, which is often implicated in various pain conditions within the body. *Vednadhyay* addresses the symptomatic manifestations of various disorders in paediatric patients and is an invaluable resource for paediatric examinations. Consequently, the current study is based on the original text from this chapter and explores the implications of *Udarshula* (abdominal pain) within the context of contemporary medical science [2].

Chronic abdominal pain is experienced by approximately 10-12% of school-aged children with nearly 20% affected in middle and high school populations [3]. In the field of paediatric medicine, abdominal pain may serve as an indication of underlying pathological conditions or may constitute a disorder in its own right. *Udarshula* is predominantly associated with *Vata* and *Kapha doshas*, and *Shatyadi Yoga* is recognised as a suitable formulation for their pacification. However, there is a notable absence of research data concerning this formulation. Dicyclomine is a standard pharmacological intervention employed for abdominal colic in children.

The management of abdominal pain in paediatric patients presents several challenges, particularly due to the limitations in communication by young children. As a result, caregivers often provide interpretations of the child's distress, which can be instrumental in identifying the underlying cause. Furthermore, conducting a thorough abdominal examination in young children is inherently challenging [4]. Recurrent Abdominal Pain (RAP) is a common occurrence, affecting approximately 10%-20% of school-aged children [3]. A few Ayurvedic formulations are available in syrup form for the treatment of *Udarshula*. Such syrup formulations are not only palatable but also facilitate ease of administration in the paediatric population [5].

A variety of medications, including probiotics, simethicone, dicyclomine, Bonnyspas, and Caspa drops, are available in the pharmaceutical market. Certain treatments, such as probiotics, may be prohibitively expensive for some families. Syrups present an appealing alternative due to their palatability and ease of administration [4]. Moreover, some medications lack empirical evidence supporting their use in the treatment of *Udarshula* (infantile colic). Therefore, the formulation selected for this study is characterised by its *'deepana'* (carminative) and *'pachana'* (digestive) properties, as well as its capacity to alleviate pain (*'shula prashaman'*) [6]. These characteristics indicate that it may effectively relieve abdominal pain by addressing *Vata dosha*, while being suitable for uniform climates and seasons and accompanied by dietary monitoring and maternal activities.

REVIEW OF LITERATURE

In Ayurveda, indigestion caused by an impaired Vata Dosha often results in abdominal pain known as Udarshula. This condition is

linked to the suppression of natural urges (Vegadharana), which leads to Vata accumulation. Classical texts address Udarshula in various ways: the Kashyapa Samhita discusses it in the context of Vridhi-Gulma-Shoola-Udarachikitsa, while the Sushruta Samhita covers it in Gulmapratishedhadhyaya. The Madhava Nidana elaborates on its various forms and causative factors [7].

Infantile colic, or Udarshula in Ayurvedic terminology, has been the focus of several clinical investigations exploring both traditional and non-pharmacological therapies. Kapatkar S et al., (2024) evaluated the efficacy of Vyoshadi Yoga (administered with honey) compared to Simethicone drops in 40 infants. Both groups showed significant improvement in colic symptoms, assessed via FLACC scale, subjective criteria, and parental questionnaires ($P < 0.05$). The therapeutic effects persisted through a 28-day follow-up, and no adverse reactions were reported. The authors concluded that Vyoshadi Yoga is as effective as simethicone and recommended larger trials for further validation [8].

In a 2020 open-label study, Sachchidanand et al., investigated the efficacy of Sauvarchaladi Churna with honey in 36 infants under six months. Assessments conducted at intervals from 10 to 180 minutes post-administration revealed marked reductions in crying frequency, leg pulling, facial flushing, and feeding refusal. No side-effects were observed, supporting the formulation's efficacy in managing infantile colic [9].

Patil D et al., examined Shatapushpa Arka in infants during the Ksheerpakavastha stage and reported significant symptom relief by day 3 of treatment compared to baseline, suggesting its potential benefit in alleviating Udarshula symptoms [10].

A case documented by Songara S et al., assessed the use of Vyoshadi Yoga in a three-month-old exclusively breastfed infant presenting with classical features of Udarshoola. The regimen consisted of 125 mg administered twice daily with honey for 14 days. Following treatment, pain episodes decreased by 66%, nocturnal awakenings by 67%, and abdominal rigidity by 75%, with no reported adverse effects. The authors concluded that Vyoshadi Yoga appears to be a safe and effective intervention for infantile colic, though further clinical validation is recommended [11]. Shatyadi Yoga, a classical Ayurvedic formulation, offers a potentially safer alternative but lacks comparative clinical evidence. This study proposes to evaluate both treatments to support integrative, evidence-based paediatric care. It addresses the need for safer, effective options and bridges gaps in Ayurvedic research. The present study aims to evaluate and compare the efficacy of *Shatyadi Yoga* versus Dicyclomine syrup in the management of *Udarshula* (abdominal pain) in children.

Primary Objective

1. To study the efficacy of *Shatyadi yoga* in the management of Abdominal pain in children.
2. To study the effectiveness of dicyclomine in the management of abdominal pain.

Secondary Objective

To compare the effectiveness of *Shatyadi yoga* vs the active control (dicyclomine) in the management of abdominal pain (*udarshula*).

- **Null Hypothesis (H0) -** There is no difference in the efficacy of *Shatyadi Yoga* as compared to the Active control (dicyclomine syrup) in treating *Udarshula* (abdominal pain) in children.
- **Alternative Hypothesis (H1):** Shatyadi Yoga is more efficacious than the Active control (dicyclomine syrup) in treating *Udarshula* (abdominal pain) in children.

MATERIALS AND METHODS

A randomised, double-blind superiority clinical trial will be conducted at Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (H), Wardha, Maharashtra, India, from February 2025 to January 2026. The ethical approval is obtained from the Institutional Ethical Committee (IEC) (MGACHRC/IEC/Jun-2024/828). The trial was prospectively registered on the CTRI with reference number CTRI/2024/08/072196. Before the trial commences, informed consent will be obtained from the parents/Guardians. Children of either sex aged between 2 to 10 years, presenting with classical signs and symptoms of *Udarshula* (abdominal pain), will be considered eligible for the study. Only those whose parents or legal guardians provide informed written consent will be included. Children who have undergone deworming treatment for worm infestation, and those residing in uniform geographical and seasonal conditions, will also be considered for inclusion. Furthermore, only patients scoring between 0-6 on the FPS-R [12] will be selected.

Participants will be excluded if they suffer from any infectious diseases such as tuberculosis or HIV systemic illnesses, congenital abnormalities, malignancies, or malabsorption syndromes, including irritable bowel syndrome or metabolic disorders. Additionally, children whose parents do not consent to participation and those scoring between 7-10 on the FPS-R will not be included in the study.

Withdrawal criteria: The patient is not taking proper follow-up, whose symptoms do not resolve even after six doses of medicine, will be withdrawn.

Sample size calculation: The means of time spent crying (the primary outcome) in the two treatment groups were used to calculate the sample size:

$n \geq \{(Z\_(1-\alpha/2) + Z\_(1-\beta))^2 * (\sigma 1^2 + \sigma 2^2/r)\}/(\mu 1 - \mu 2)^2$

Group 1 (Shatyadi) mean=4.9 hours/day (SD=3.7),

Group 2 (dicyclomine) mean=3.3 hours/day (SD=3.0) [13].

Using a two-sided significance level α=0.05 ($Z1-\alpha/2$=1.96) and power 80% ($Z1-\beta$=0.84), the required sample size per group was computed as:

$$n \geq \frac{(1.96+0.84)^2(3.7^2+3.0^2)}{(4.9-3.3)^2} \approx 69.5$$

Sample size (n) = 178.09/ 2.56 =70 per group.

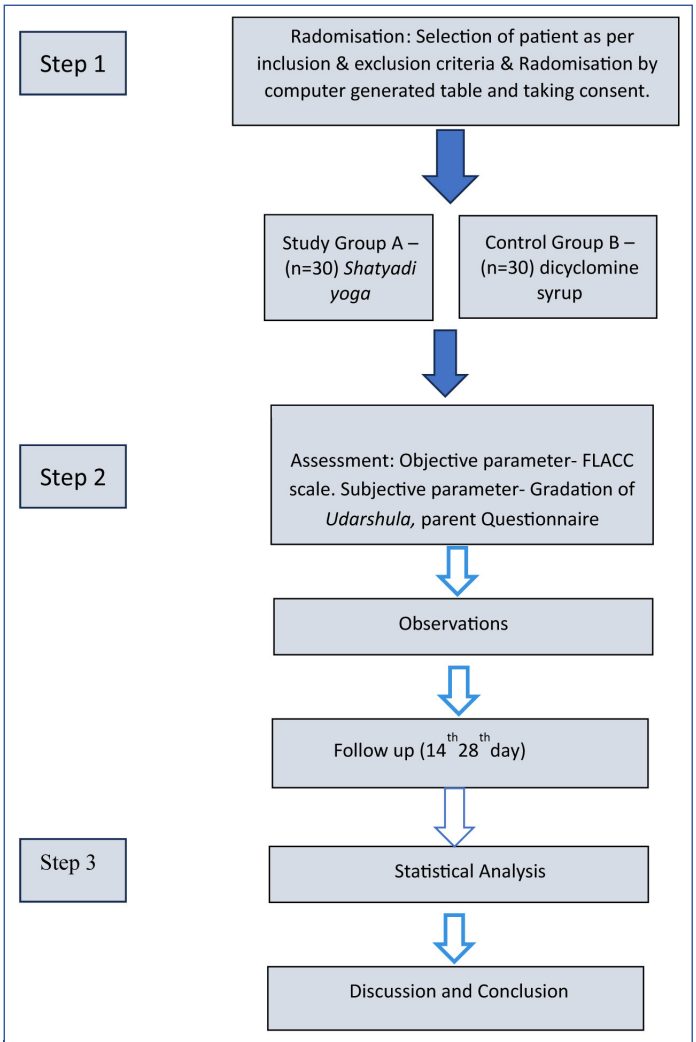
Although the calculated sample size was 140 participants (70 per group), our trial design is guided by institutional feasibility criteria. As specified in the CTRI registration, the approved sample size for the study is 60 participants in total (30 per group). The Institutional/College Ethics Committee permitted a maximum recruitment of 60 participants, taking into account feasibility within the study period and available resources. This discrepancy between the calculated and actual sample size arose because the CTRI registration and trial conduct followed institutional feasibility constraints, whereas the manuscript referenced the calculated value from prior work. A post-hoc power analysis will be performed for each outcome variable upon completion of the study.

Participants will be randomised in a 1:1 ratio to either the intervention group or the control group, with 30 individuals allocated to each arm. The randomisation sequence will be computer-generated using permuted blocks of variable size to ensure balanced group sizes throughout enrolment while minimising predictability. The randomisation sequence will be prepared in advance by an independent statistician who is not involved in participant recruitment or assessment. Allocation concealment will be maintained using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) or a secure, password-protected web-based system, depending on site resources.

In this double-blind superiority clinical trial, both the participants and outcome assessors will remain blinded to minimise bias.

Group-A will receive *Shatyadi Yoga* administered twice daily with water as Anupana for 14 days [8], while Group-B served as the

active control, receiving Dicyclomine syrup with the same dosage schedule and duration [Table/Fig-1,2].



[Table/Fig-1]: Flowchart depicting the study protocol.

Group	Sample size	Intervention	Dose and frequency	Anupana	Duration	Review
Group-A	30	Shatyadi Yoga	BD	Water	14 days	Follow-up after 7 days of treatment
Group-B	30	Active controlled of dicyclomine syrup	BD	Water	14 days	Follow-up after 7 days of treatment

[Table/Fig-2]: Posology of the drugs.

Raw medications will be sourced from credible sources and validated by the Department of Dravya Guna at Mahatma Gandhi Ayurveda College, Hospital & Research Centre in Salod (Hirapur), Wardha.

Shatyadi Yoga will be prepared following classical methods at the GMP-certified Dattatraya Rasashala, adhering to standard protocols as prescribed in the Ayurvedic Pharmacopoeia of India and Schedule T of the Drugs and Cosmetics Rules, 1945, for good manufacturing practices in Ayurvedic medicine production [14-16], and will be analysed in a pharmaceutical laboratory. Dicyclomine hydrochloride syrup will be procured from a reputed and licensed pharmaceutical company and will be sourced through the institutional pharmacy or an authorised medical distributor. The batch number, expiry date, and manufacturer details will be recorded and maintained for quality assurance and audit purposes. Drugs will be administered twice daily for 14 days.

Raw herbs and other components will be meticulously cleaned to remove soil, dust, foreign particles, and other physical impurities. Specific *Shodhana* (purification) procedures will be applied if required as per Ayurvedic texts.

The herbal ingredients will be coarsely powdered and subjected to decoction preparation using the standard *kwatha vidhi* (decoction method), maintaining the recommended ratio of drug to water and reducing it to the specified quantity.

The decoction will be filtered using a muslin cloth and concentrated further under controlled heat to obtain the required consistency.- The concentrated decoction will then be blended with sugar or jaggery (as per formulation requirement) and processed into syrup form using the standard syrup preparation method, ensuring proper homogenisation [15,16].

Addition of Emulsion (if applicable)

The syrup will be passed through fine filtration, and parameters like viscosity, pH, microbial load, and organoleptic properties will be analysed in a pharmaceutical laboratory for quality assurance. The prepared syrup will be filled into sterilised bottles in a clean environment. Each bottle will be sealed properly and labelled with batch details, manufacturing date, expiry date, and dosage instructions.

Outcomes

Subjective criteria: A clinical scoring system will be used for assessing the severity of *Udarshula* (abdominal pain) and its associated symptoms in paediatric patients. The scoring criteria are adapted from validated Ayurvedic paediatric pain assessment methods [17]. Each symptom- *Shoola* (pain intensity), *Udarapūrana* (abdominal distension), *Aruchi* (loss of appetite), *Vibandha* (constipation), and *Chardi* (vomiting) will be graded on a four-point ordinal scale.

Objective criteria: FPS-R is a self-reported measure of pain intensity that requires little time and very few instruments, like the photocopied faces, to administer. The clinician scores the chosen face 0, 2, 4, 6, 8, or 10, counting left to right from the six series of faces [12]. Each category is scored on the 0-2 scale. This results in a total score of 0-10.

Assessment of parent questionnaire: The questionnaire comprised 11 structured items addressing infant feeding history, gastrointestinal symptoms, bowel habits, and parental interventions prior to consultation. It was specifically developed to capture the clinical features of *Udarshula* (infantile colic) within the study population. The tool was adapted from previously published and validated infant colic assessment instruments [18], thereby ensuring both content validity and reliability in the context of paediatric gastrointestinal disorders. For the present study, the questionnaire will be suitably modified to align with the population and objectives, with particular emphasis on gastrointestinal symptoms and parental observations relevant to *Udarshula* (abdominal pain). Formal permission for these modifications will be obtained from the original authors before data collection.

Assessment of Behavioural Score [19]: The FLACC provides a simple framework for quantifying pain behaviours in children who may not be able to verbalise the presence or severity of pain. Relaxed and Comfortable=0, Mild discomfort=1-3, Moderate pain=4-6.

STATISTICAL ANALYSIS

Statistical analysis for the present study will be performed using IBM SPSS Statistics version 17. Quantitative data will be analysed using paired t-tests for within-group comparisons to assess changes over time, and unpaired t-tests for between-group comparisons to evaluate differences between intervention groups. For qualitative data, the Chi-square test will be applied to examine associations between categorical variables. A significance level of $p<0.05$ will be considered statistically significant for all inferential tests. In addition

S. No.	Drug name	Latin name	Part used	*Rasa*	*Virya*	*Vipaka*	*Guna*	*Doshaghnata*	*Gana*
1.	Shati *[14]*	Hedychium spicatum Buch	Rhizome	*Katu Tikta*	*ushna*	*Katu*	*Laghu* and *Teekshna*	*Kaphavataghna*	*Deepaniya, shulaprashaman(ch)*
2.	Pushkar *-mula*	Inula racemose Hook	Root	*Tikta Katu*	*ushna*	*Katu*	*Laghu, tikshna*	*Vatakaphaghna*	*Deepaniya, shulaprashaman(ch)*
3.	*Pippali*	Piper longum Linn.	fruit	*Katu*	*Anushna*	*Madhura*	*Laghu,snigdha, tikshna*	*Vatakaphagghna*	*Deepaniya, shulaprashaman(ch)*
4.	*Brihati*	Solanum indicum Linn.	Root	*Katu Tikta*	ushna	Katu	*Laghu, Ruksha*	Vata-kaphaghna	Kanthya Shothhar (ch)
5.	*Kantakari*	Solanum xanthocarpum Schard.	Whole plant	*Titkta, Katu*	*ushna*	*Katu*	*Laghu, tikshna*	Vata-kaphaghna	*Agnimandya prashanama(ch)*
6.	Shunthi	Zingiber officinalis. Roxb	Roots	*Katu*	*ushna*	*madhura*	*Laghu& snigdha*	Kapha-vataghna	*Deepaniya, shulaprashaman(ch)*
7.	*Karkatshringi*	Pistacia chinensis	Galls	*Kashaya* Tikta	Ushna	Katu	*Laghu Ruksha*	Kasahara	*Kasahara*
8.	*Bharangi*	Clerodendrum serratum Linn.	Roots	*Tikta Katu*	*Ushna*	*Katu*	*Laghu Ruksha*	Kapha-vataghna	*Pachak*
9.	*Duralabha*	Fagonia cretica Linn.	Whole plant	*Madhura Kashaya*	*Sheet*	*Madhura*	Laghu and snigdha	Vatapitta Shamaka	
10.	*Yavanika*	Trachyspermum ammi	Fruits	Katu- Tikta	ushna	Katu	Laghu, tikshna, snigdha	Vta- kaphaghna	

[Table/Fig-3]: Ingredients of *Shatyadi Yoga* along with their respective parts used, rasa (taste), guna (qualities), vipaka (post-digestive effect), and doshagnata (dosha-pacifying action).

to these analyses, descriptive statistics such as means, standard deviations, and percentages will be calculated to summarise baseline characteristics and outcome measures, providing a comprehensive overview of the study population and treatment effects.

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[Table/Fig-4] presents the Gantt chart outlining all phases from protocol approval to thesis submission.

Scholar/ Investigator	Dr. Prachi Vijay Warukar					
Title	"Evaluation of comparative efficacy of *Shatyadi Yoga* versus Dicyclomine Syrup in the management of *Udarshula* (abdominal pain) in children-A randomised controlled trial"					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Approval from IEC						
Review of literature						
Drug preparation						
Enrolment of the patients						
Data collection						
Statistical analysis						
Thesis writing						
Submission						

[Table/Fig-4]: Gantt chart outlining all phases from protocol approval to thesis submission.

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