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Study Protocol

OPEN LABELLED RANDOMIZED TRIAL TO EVALUATE THE EFFICACY OF *AJAMODA ARKA* WITH *YAVA KSHARA* AND *SHATAPUSHPA ARKA* IN *VATAJA UDARSHOOLA* (INFANTILE COLIC).

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ABSTRACT :

INTRODUCTION: Infantile colic is a common concern among primary care physicians and childcare providers. Prevalence rates vary significantly, with prospective studies reporting a range of 3% to 28% and retrospective studies 8% to 40%. In Ayurveda, *Udarashoola* (colic) is a condition where in infant rejects the breast, cries persistently, difficulty in lying supine position, experiences abdominal stiffness and exhibits facial perspiration with cold and clamy extremities. *Shoola* (colic) is primarily due to imbalance of *Vata* (Vayu). Distressing cry of infantile colic disturbs mother and caregivers. If left untreated, it may lead to poor weight gain and a diminished quality of life in infant. Number of traditional remedies, standard prescriptions to manage infantile colic are in vogue but are also associated with adverse effects. Traditional prescriptions containing jeera, dil seeds, methi does give relief though are not scientifically documented. Recently probiotics are being used as part of scientific advancements to treat infantile colic. Thus this study aim to explore a traditional prescriptions containing *Ajamoda arka* with *Yavakshara* along with buttermilk on infantile colic. **MATERIALS AND METHODS:** This is a prospective, open-label, randomized controlled clinical trial of total of 50 participants diagnosed with infantile colic. **Trial group:** Subjects in the **trial group** will be treated with *Ajamoda Arka* with *Yavakshara* as follows: **Infants aged 1 to 3 months:** 0.5 ml *TID* with 1 ml *Takra* (buttermilk) **Infants aged 4 to 5 months:** 1 ml *TID* with 2 ml *Takra*. The treatment will be administered for 15 days, with *Takra* as an *Anupana* (vehicle). **Control Group**: Subjects in the control group will receive *Shatapushpa Arka* alone in the similar way. **CONCLUSION:** The study's findings may potentially demonstrate that the Ayurvedic intervention of *Ajamoda Arka* with *Yavakshara* is as effective as *Shatapushpa Arka* in managing *Vataj Udarashoola* (infantile colic).

KEYWORDS: *Udarshoola*, infantile colic, *shoola*

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1. BACKGROUND AND RATIONALE

Infant crying patterns vary with age. Infantile colic is characterized by sudden, inconsolable and spontaneous crying episodes that are mostly erratic but without an identifiable cause in an otherwise healthy new-born.[1,2] In most infants the onset of Colic starts typically in the first month of infancy and starts reducing by 3 to 4 months of life though in some cases, it can persist up to 12 months. It is considered a pain syndrome, often associated with digestive disturbances such as flatulence, indigestion, and abdominal discomfort, which can ultimately impact an infant's growth and weight gain. Globally, Colic is seen in 10-40% of infants.[3] It poses considerable distress to parents and care givers and if persists beyond three months then, it may associated with risk of negative impact on emotional, developmental and behavioural areas.[4] Infantile colic can be correlated with *Udarashoola* as described in Ayurvedic classics, characterized by symptoms such as *Sthana Vyudasyate* (refusal to breastfeed), *Rauti* (excessive crying), *Uttanaschavabajyate* (difficulty in lying supine position), *Udara Stabdata* (abdominal distension), *Shaityam* (sensation of cold) and *Mukhasweda* (facial perspiration). [5] *Aggravated Vayu, due to various causative factors, leads to intense cutting and spasmodic pain within the abdominal cavity (Koshta)*.[6]

Various medications have been used to manage colic, including dicyclomine hydrochloride, cimetropium bromide, simethicone, sucrose, and certain herbal remedies often administered with parental reassurance. These agents primarily serve as pain relievers. However, some of them carry potential side effects, such as respiratory difficulties and, in rare cases, coma.[7-8]

Uses of lactase supplements and probiotics have been recent advancements with good effect. A few recent studies conducted in the Indian context highlight the need for a practical, effective, and acceptable intervention for managing infantile colic. Use of gripe water, though a common practice but not recommended by WHO because of no proven benefits.[9] There are isolated studies on use of Fennel seed oil (65% relief in colic), *Mentha piperita* oil.[10] with some relief, COLIC CALM (suspension consisting of vegetable charcoal, Blackthorn, Caraway, Chamomile, Fennel, Ginger, Lemon Balm and Peppermint showed significant relief in colic.[11] All these studies prove the utility of herbal remedies in the colic context. There have been studies on *Hingvashtaka arka,* [12] *Shatapushpa arka* on infantile colic with proven efficacy in Ayurveda. Still there exists a lacuna in the field due to lack of controlled studies. Thus in the current study an effort is done to establish a classical medication mentioned in the context of consisting of traditional *balachikitsa* namely *ajamoda* (*Apium graveolens)* with *yavakshara* (*Hordeum vulgare* Lio) and *takra* (butter milk) [13] through a controlled clinical trial in infantile colic. The proposed drug shall be in the form of *Arka* (Aqueous distillate extract of *Ajamoda* dissolved with *Yavakshara*) to be administered with buttermilk.

Here *Ajamoda Arka* and *Yavakshara* with *takra* are used for the treatment of *Udarashoola*. In recent times probiotics are administered in the management of infantile colic with fairly good results. Considering this

fact and classical *Ajamoda arka* and *Yavakshara* will be very useful in infantile colic. Most common probiotics preferred to be used are of *Lactobacillus, Bifidobacterium and Streptococcus* and *takra* is rich in probiotics and also useful in low digestive power due to its ability of balance *tridoshas*. Growing evidence suggests that the gut flora of infants with colic differs from that of healthy babies, supporting the hypothesis that probiotics aid in restoring the gut milieu. Thus takra can be an easily available source of probiotics which can act like any other common low cost probiotics can have potential to Reduce the occurrence and frequency of infantile colic.[14]

2. OBJECTIVES:

To evaluate the effect of Ajamoda Arka and Yavakshara on daily average crying and fussiness in infants with *Vataja Udarshoola* (colic) using the Fussiness Rating Scale. [15]

To assess the impact of Ajamoda Arka and Yavakshara on pain associated with *Vataja Udarshoola* in infants using the "FLACC Behavioral Pain Scale".[16]

To determine the effect of *Ajamoda Arka* and *Yavakshara* on gastrointestinal discomfort in infants with *Vataja Udarshoola* based on the Infant Gastrointestinal Symptom Questionnaire (IGSQ) Score.[17]

To compare the effectiveness of Ajamoda Arka and Yavakshara with the standard Shatapushpa Arka in managing pain and symptoms of *Vataja Udarshoola* in infants.

Study Design

An open label Randomized, controlled clinical, parallel groups trial**.** The primary outcome is the daily average crying and fussiness due to colic in infants, assessed using the Fussiness Rating Scale. Pain severity will be evaluated based on the "FLACC behavioural pain" grading system, while gastrointestinal symptoms will be measured using the IGSQ (Infant Gastrointestinal Symptom Questionnaire) score. The trial will be conducted over a period of 15 days.

Study Setting

Outpatient and inpatient department of Shree Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru.

Study Duration:

Total duration of clinical study is 15 days

Eligibility Criteria

ICD-10-CM,CODE R10.83

Written informed consent shall be taken prior to participating in the study.

Inclusion criteria:

- Infants of either gender diagnosed with colic according to the "ROME IV criteria".
- Infants aged between 1 to 5 month.
- Infants experiencing recurrent and prolonged episodes of crying, irritability and fussiness, with no identifiable cause and are not alleviated by typical comforting measure.
- Full-term, healthy neonates.
- Mothers and caregivers who are willing to participate and provide written informed consent.

Exclusion criteria:

- Infants with disorder of bowel or urinary tract disorders that might present as abdominal

distension, inguinal swelling or scrotal swelling.

- Infants with chronic or acute systemic illnesses of gastrointestinal, Respiratory etc.
- Infants with known chromosomal, metabolic, or hereditary disorders.
- Infants or there who are on medication or diet that may interfere with study objectives.
- Breast feeding mothers or their kids on antibiotic therapy in the last 15 days.
- Mothers who consume alcohol, smoke and tobacco.
- Infants who are on formula feed or animal (feed) milk.

Interventions

Treatment of the trial group will include oral administration of *Ajamoda arka* with *Yava kshara* along with *Takra* (Buttermilk) as *Anupana* for a period of 15 days1.

The control group will receive oral administration of Shatapushpa Arka for duration of 15 days. The detailed study schedule is described in table1.

Table 1: Study Schedule

Study event	Baseline	Day 1	Day 7	Day 15
Baseline assessment (FUSSINESS RATING SCALE,FLACC SCALE,IGSQ SCORE)	✓			
Informed consent	✓			
Recruitment	✓			
Demographic profile	✓			
Intervention (15 days)	✓	✓	✓	✓
Follow-up		✓	✓	✓
Assessment by clinical evaluation	✓	✓	✓	✓
Evaluation using the assessment parameters (FUSSINESS RATING SCALE,FLACC SCALE,IGSQ SCORE)		✓	✓	✓
Drug compliance	✓	✓	✓	✓
Rescue medication (If required)		✓	✓	✓
Assesment of adverse events		✓	✓	✓

Discontinuation/modification criteria: In the event of an emergency, rescue medicines may be administered at the discretion of the Principal Investigator. All such instances must be documented in the appropriate section of the Case Record Form.

Adherence monitoring strategy: Patient advised to keep track of symptoms and report via electronic media.

Outcomes

Primary outcome measure:

1) Reduction in the clinical features of *Vataja udara shoola*.

2) Reduction in the Intensity of cry & fussing by FUSSINESS rating scale.

Secondary outcome measures:

1) Decreased in Pain, Activity and sleep behaviour based on FLACC scale.

2) Improvement in the Gastro intestinal features- IGSQ score.

Sampling Size:

The sample size was calculated using a standard formula.

Sample size has been calculated based upon the Standard deviation of Previous Clinical study.

$$N = \frac{2(SD)2 \times [Z(1-\alpha) + Z\beta]2}{d2}$$

SD=59.96; expected difference between the group

Zβ=this depends on power on power, for 80% this is 0.84

Z(1-α)=1.96 (at 5% significance level)

d = 50

10% drop out

Total sample size,

$$N = \frac{2(59.96)2 \times (1.96+0.84)2}{(50)2} = \frac{56082}{2500} = 22$$

Total sample size based upon formula is 22

Considering 10% drop out, N=25.

25 in each group will be taken.

Recruitment:

Study group: 25 infants under the age group of 5 months visiting kaumarbhritya OPD of SDM Bengluru with features of *Vataj Udarshoola* will be taken for the study

Control group: 25 infants under the age group of 5 months visiting kaumarbhritya OPD of SDM Bengluru with features of *Vataj Udarshoola* will be taken for the study

Allocation and concealment: Random allocation using computer generated random tickets which will be kept labelled in a Opaque sealed cover, to be opened in front of guide while starting the intervention.

3. METHODS

Current research will be an open-label, interventional, prospective randomized controlled clinical trial .

3.1 Data Collection Method:

Data collection will be carried out with a customized Case Report Form (CRF), and assessments will utilize the Fussiness Rating Scale, the FLACC Scale, and the IGSQ Score.

3.2 Data Management

Specific Case Report Form (CRF) will be used to collect detailed data and later it will be exported to MS Excel and statistical analysis will be done using IBM SPSS Version 26.

3.3 Statistical Methods:

For statistical analysis, data will be collected using a specially designed Case Report Form (CRF) encompassing all aspects of the study and compiled into an MS Excel spreadsheet. The data will be tabulated, and analysis will be performed using IBM SPSS Version 26.

Descriptive Statistics:

Base line data will be analyzed using descriptive statistics in terms of frequency, percentage, and range. Median and percentages will be used to analyze nominal and ordinal data, while mean and standard deviation for continuous data.

Inferential Statistics:

To infer the clinical study and to draw conclusions Parametric and Non-Parametric tests will be applied accordingly.

Level of Significance: A p-value of <0.05 will be considered statistically significant.

Non-Parametric Tests:

- For subjective data, the Wilcoxon Signed-Rank Test will be used to evaluate within-group differences before and after treatment.
- The Mann-Whitney U Test will be employed to compare differences between the trial and control groups.
- For comparisons involving more than two sets within the same group, Friedman's Test will be applied.

Parametric Tests:

- For objective data, the Paired t-test will be used to assess within-group differences before and after treatment.
- The Unpaired t-test will be used to compare differences between the trial and control groups.

Categorical Data:

- Categorical variables will be analysed using the Chi-Square Test.

Effect Size:

- Effect size will be calculated using Cohen's d formula.

3.5 Data Monitoring

The researcher and guide will monitor data, ensures adherence to the treatment protocol, tracking adverse effects, and managing participant enrolment.

Auditing: Since it is a small trial external audit is not applicable.

Adverse Effect Management and Safety Measures

Although there are no anticipated serious side effects, any unexpected events that may come across during the study will be documented and notified to concerned authority. Prior to the study, parents shall be asked to disclose any known food allergies. All significant adverse events will be recorded in final report.

Ethical Issues and Informed Consent

Ethical approval for the trial was obtained from the Institutional Ethics Committee of SDMIAH on October 3, 2023 (Ref: SDMIAH/IEC/33/2023) and was registered in Clinical Trials Registry of India (CTRI) on June 24, 2024 (CTRI/2024/07/070107). The study will adhere to the ethical principles outlined in the Declaration of Helsinki. Written informed consent will be obtained prior to enrollment in to trial. Participation will be entirely voluntary, with the option to withdraw at any point of time. The final trial dataset will be anonymized and accessible only to the primary investigator, designated data auditors, and study supervisor. Patient data will be kept strictly confidential. In the event of any adverse events, appropriate will be provided.

Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable – not applicable

Declaration of interests- there are no conflicts of interest.

Study Status

Open for recruitment

Dissemination

Upon completion of the trial, a research paper outlining the original findings will be published in an open access indexed journal for publication so as to reach wider scientific population. Further, a structured awareness program will be organized to reach out people in community.

4. DISCUSSION

Colic is estimated to affect approximately 10% to 40% of infants worldwide. It often leads to parental distress, and if it continues more than three months, it may increase the chances of negative behavioural, developmental and emotional outcome in babies. There have been studies on *Hingvashtaka arka, Shatapushpa arka* on infantile colic with proven efficacy in Ayurveda. Still there exists a lacuna in the field due to lack of controlled studies. Thus in the current study an effort is done to establish a classical medication mentioned in the context of consisting of traditional balachikitsa namely *ajamoda* (*Apium graveolens)* with *yavakshara* (*Hordeum vulgare* Lio) and *takra* (butter milk) for infantile colic through a randomized controlled trial.

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