



**International Journal of Biology, Pharmacy
and Allied Sciences (IJBPAS)**
'A Bridge Between Laboratory and Reader'

www.ijbpas.com

EFFICACY OF ARJUNADI CREAM IN AHIPUTANA (DIAPER DERMATITIS) IN INFANTS: A RANDOMIZED COMPARATIVE CONTROLLED CLINICAL STUDY PROTOCOL

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Received 8th March 2026; Revised 10th April 2026; Accepted 18th June 2026; Available online 1st Nov. 2026

<https://doi.org/10.31032/IJBPAS/2026/15.11.10583>

ABSTRACT

Introduction: *Ahiputana*, clinically correlated with diaper dermatitis, is a common inflammatory skin condition in infants caused by prolonged exposure to moisture, urine, and faeces. In *Ayurveda*, it is described under *Kshudra Rogas*, primarily involving vitiation of *Kapha*, *Pitta*, and *Rakta*, leading to symptoms such as erythema, itching, discharge, and lesions. The prevalence ranges from 4% to 35% in early childhood. Conventional topical therapies provide symptomatic relief but may be associated with adverse effects on prolonged use. *Arjunadi Lepa*, possessing anti-inflammatory and wound-healing properties, is explored in a modified cream form to enhance therapeutic efficacy and acceptability.

Methods: A randomized, open-label, parallel-group clinical trial will be conducted on 120 infants diagnosed with *Ahiputana*. Participants will be randomly allocated into two groups (n=60 each). Group A will receive *Panchavalka* ointment, and Group B will receive *Arjunadi* cream, applied locally thrice daily for 7 days. Primary outcomes will be assessed using the Diaper Dermatitis Severity Scale, while secondary outcomes include the FLACC scale for pain and ItchyQuant scale for itching, evaluated on Day 0, 8 and 15. **Expected Outcomes:** The study is expected to demonstrate significant improvement in both groups, with *Arjunadi* cream showing enhanced efficacy in reducing erythema, itching, discharge, and lesions. Improved patient compliance and faster healing response are anticipated.

Conclusion: This study aims to establish *Arjunadi* cream as a safe, effective, and child-friendly alternative in the management of *Ahiputana*, contributing to evidence-based *Ayurvedic* practice.

Keywords: *Ahiputana*, Diaper Dermatitis, *Arjunadi* Cream, *Panchavalka* Ointment, *Ayurveda*, Randomized Controlled Trial

1. INTRODUCTION

Diaper dermatitis is a general term used to describe inflammatory skin lesions occurring in infants due to prolonged exposure to irritants such as urine, feces, sweat, and retained moisture from diaper use [1]. The reported prevalence ranges between 4% and 35% [2]. It is most frequently observed in children below 24 months of age, often beginning in the neonatal period with the initiation of diaper use. In *Ayurvedic* literature, diaper dermatitis can be correlated with *Ahiputana*, described under *Kshudraroga* in the *Sushruta Samhita* [3]. Additionally, the *Ashtanga Hridaya* mentions similar conditions using terms such as *Gudakuttaka*, *Matrukadosha*, *Ahiputana*, *Prishtaru*, and *Anamaka*, each highlighting different clinical features of the disease [4]. According to *Acharya Sushruta* and *Vagbhata*, *Ahiputana* primarily results from the vitiation of *rakta* (blood) and *kapha dosha*. The etiological factors include inadequate cleaning of the perianal region following defecation and urination, often attributed to maternal negligence, hence termed *Matrukadosha*. Other contributing factors include vitiated breast milk, as explained by commentators *Gayadasa* and *Bhoja* [5]. The condition is also associated

with *Putana Graha*, which is described as an infectious diarrhoeal disorder under *Graharoga* (sepsis) [6]. *Indu* interprets the term *Pouthana* as a disorder arising from *Putana dosha*, thereby justifying the nomenclature *Ahiputana* [7]. This association suggests a possible comorbidity between diaper dermatitis and diarrhoeal conditions. *Acharya Kashyapa* emphasizes that the delicate skin (*twak*) of infants is highly susceptible to damage due to factors such as tight clothing, warm environmental conditions, excessive sweating, and prolonged contact with urine and faeces, along with improper hygiene practices and friction caused by powders [8]. Regarding management, *Vagbhata* highlights the involvement of *kapha* and *pitta doshas* in both mother and child and recommends therapeutic measures aimed at their pacification, particularly in breastfeeding mothers. The principles of *Pitta Vrana Chikitsa* (management of *pitta*-dominant wounds) and *Raktamokshana* (bloodletting) further emphasize the role of *pitta* and *rakta* in the pathogenesis of *Ahiputana*. The primary tissue involved is *twak*, which is an *upadhatu* of *rasa dhatu*. Additionally, the role of *malas* specifically *sakrit* (feces),

mutra (urine), and *sweda* (sweat) is significant, not only due to their local irritant effect (*upalepa*) but also due to their pathological vitiation, particularly of *sakrit*, influenced by *kapha-pitta dushti* in breast milk and the presence of *Putana Graha* [9, 10]. *Arjunadi Lepa* is a powerful *rakta-prasadaka* (blood-purifying) and *twak-prasadaka* (skin-enhancing) formulation. Long-term use of modern creams may cause side effects in children; therefore, we have planned to formulate *Arjunadi* cream as a safer and more effective alternative for treating diaper dermatitis. The present study aims to evaluate the therapeutic effect of *Arjunadi* cream in the management of *Ahiputana* in children up to 1 year of age, and to comparatively assess its efficacy with *Panchavalkala* ointment. Additionally, the study intends to prepare and standardize

Arjunadi cream in accordance with standard operating procedures, evaluate its safety profile, and analyze its clinical effectiveness in reducing the signs and symptoms of *Ahiputana*.

2. STUDY DESIGN AND SETTINGS

This study is a randomized, open-label, comparative clinical trial. Subjects will be recruited from the outpatient and inpatient departments (OPD/IPD) of *Kaumaraabhritya* at Khemadas Hospital. Following a comprehensive screening for eligibility and the acquisition of informed assent, participants will be allocated to study groups using a simple random sampling technique. The study plan of participants, from enrollment through analysis, is delineated in the accompanying CONSORT flow diagram, as mentioned in **Figure 1**.

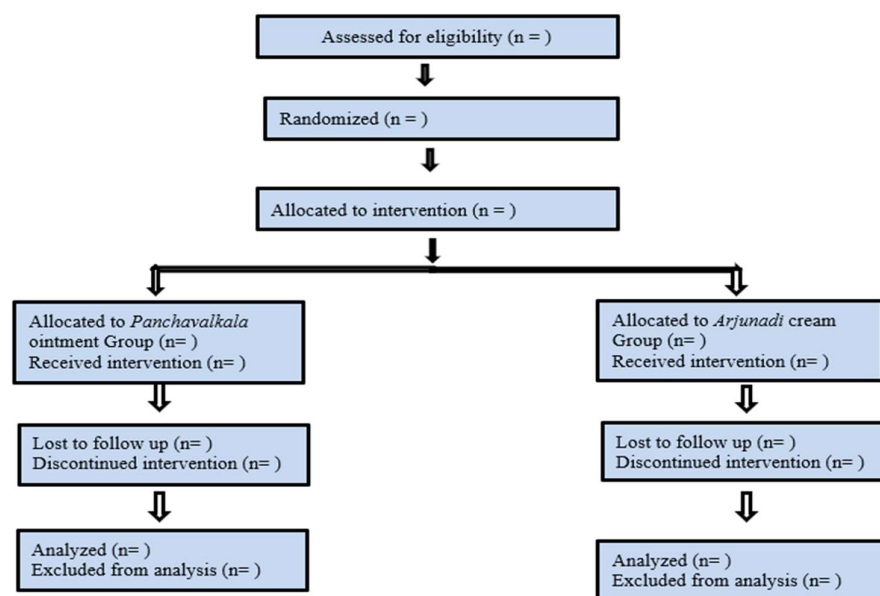


Figure 1: Proposed Study plan

3. INCLUSION AND EXCLUSION CRITERIA:

The study population will consist of infants aged between birth to 12 months, regardless of gender, socioeconomic status, or religious background, who present with a clinical diagnosis of *Ahiputana* (Diaper Dermatitis). Inclusion is contingent upon the attainment of documented informed parental consent or assent and a willingness to adhere to the trial protocol.

Conversely, potential participants will be excluded if they manifest comorbid generalised dermatological conditions, such as infantile psoriasis, or secondary integumentary infections. Furthermore, infants presenting with systemic pathologies, lactose intolerance or acute gastroenteritis complicated by dehydration will be ineligible for enrollment to ensure data integrity and patient safety.

4. INTERVENTIONS AND POSOLOGY

A total of 120 eligible children will be randomized equally into two groups of 60 each. Group 1 will receive *Panchavalkala* Ointment, local application thrice daily (QS). Group 2 will receive *Arjunadi* Cream, local application thrice daily (QS). All interventions will be local applications for a duration of 7 days.

5. OUTCOME MEASURES AND TIMELINE

The primary outcome of this study is a reduction in the severity of *Ahiputana* (diaper dermatitis) as assessed by the Diaper Dermatitis Severity Scale [5], comparing the clinical effect of *Arjunadi* cream with *Panchavalkala* ointment. These assessments will be conducted at baseline (0th day), 8th day and post-treatment (15th day).

The secondary outcome of this study is an improvement in individual symptoms of *Ahiputana*, such as pain assess through FLACC Pain Rating Scale [8] and itching assess through ItchyQuant scale [4]. Also assess improvement in erythema, discharge, and lesions, along with assessment of treatment tolerability and caregiver acceptability of *Arjunadi* cream compared to *Panchavalkala* ointment. assessed at baseline (0th day) and post-treatment (15th day) to evaluate the improvement.

6. SAMPLE SIZE

Sample size will be calculated using the Cochran formula based on previous research data. Estimation with 80 % power, and 5% level of significance, a minimum of 60 participants per group will be required.

7. RANDOMIZATION AND ALLOCATION CONCEALMENT

Participants will be assigned to study groups using computer-generated random numbers, and allocation concealment will be ensured using sequentially numbered opaque sealed envelopes (SNOSE).

8. DATA COLLECTION

Data will be collected using a predesigned Case Record Form (CRF) specially prepared for the study. Comprehensive baseline data will be collected, which includes demographic information (age, gender, socioeconomic status), clinical history, duration of illness, exposure to risk factors, and prior treatment history. The clinical evaluation will encompass the classical signs and symptoms of *Ahiputana*, such as *Pidaka* (pustular or vesicular eruptions), *Daha* (burning sensation in the affected area), *Kandu* (itching), *Raga* (erythema or redness), *Srava* (discharge or oozing of fluid), and *Toda* (pricking pain or irritation). Additionally, Researchers will use the Diaper Dermatitis Severity Scale. The first assessment will occur on the 0th day, while the second evaluation will occur on the 8th day, and the third evaluation will occur on the 15th day. The researchers will assess an improvement in individual symptoms of *Ahiputana*, such as pain, itching, erythema, discharge, and lesions, along with assessment of treatment safety, tolerability, and caregiver acceptability of *Arjunadi* cream compared to *Panchavalkala* ointment. assessed at baseline (0th day) and post-treatment (15th day) to assess patient progress. The system will maintain data accuracy through continuous monitoring, which includes both entry cross-checking and protection of data confidentiality.

9. STATISTICAL ANALYSIS PLAN

All data collected during the study will be systematically documented and analysed using standard statistical software such as SPSS or GraphPad Prism. Baseline demographic and clinical characteristics of participants will be summarized using descriptive statistics. Continuous variables will be expressed as mean $\pm$ standard deviation (SD), while categorical variables will be presented in terms of frequency and percentage.

The primary outcome parameters will include *Ruja* (pain), evaluated using the FLACC Pain Rating Scale; *Kandu* (itching), assessed through the ItchyQuant scale; and objective clinical features such as *Srava* (discharge), *Raga* (erythema), and *Pidika* (papulo-vesicular lesions), which will be measured using the Diaper Dermatitis Severity Scale. These parameters will be analysed for both intra-group and inter-group differences. For comparison within groups (i.e., between baseline and follow-up observations on Day 0, Day 8, and Day 15), a paired t-test will be applied for data that follow a normal distribution, whereas the Wilcoxon signed-rank test will be used for non-normally distributed data. For comparisons between the two treatment groups *Arjunadi* cream and *Panchavalkala* ointment the unpaired t-test will be used for parametric data, and the Mann–Whitney U test will be employed for non-parametric data. To evaluate changes across multiple

follow-up intervals within the same group, repeated measures ANOVA will be used for parametric data, while the Friedman test will be applied for non-parametric data. Categorical variables, including severity grading and the occurrence of adverse events, will be analysed using the Chi-square test or Fisher's exact test, depending on data suitability. Statistical significance will be determined at a p-value of less than 0.05, with a 95% confidence interval considered for interpretation. The analysis will follow the intention-to-treat principle, and any missing values will be managed using suitable imputation techniques. Final results will be displayed using tables, bar charts, and line graphs to clearly demonstrate and compare the effectiveness of both treatment modalities in the management of *Ahiputana*.

10. DISCUSSION

Ahiputana, clinically correlated with diaper dermatitis, represents a significant dermatological concern in infancy characterized by erythema, irritation, and inflammatory lesions in the diaper area. The multifactorial aetiology involving prolonged moisture exposure, friction, and microbial colonization necessitates a therapeutic approach that is not only effective but also safe for infant skin. While conventional topical therapies provide symptomatic relief, their prolonged use raises concerns regarding adverse effects and tolerability. In

this context, *Ayurveda* offers a rational and holistic framework for management through formulations possessing anti-inflammatory, antimicrobial, and wound-healing properties. The present randomized controlled study is designed to evaluate the clinical efficacy of *Arjunadi* cream in comparison with *Panchavalka* ointment, thereby aiming to generate evidence for an effective, safe, and acceptable therapeutic alternative in the management of *Ahiputana*.

10.1 Pharmacological Basis of Major Ingredients:

The therapeutic potential of *Arjunadi* cream is attributed to the synergistic action of its constituent drugs, each possessing pharmacological properties relevant to the pathogenesis of *Ahiputana*. *Terminalia arjuna* (*Arjuna*) is rich in tannins and flavonoids, which exhibit potent anti-inflammatory, antioxidant, and wound-healing activities, thereby aiding in the reduction of erythema and promotion of tissue repair. *Neolamarckia cadamba* (*Kadamba*) demonstrates significant antimicrobial and anti-inflammatory effects, contributing to the prevention of secondary infection and alleviation of local inflammation. *Saussurea lappa* (*Kustha*) is known for its pronounced anti-inflammatory, antipruritic, and antimicrobial properties, effectively targeting symptoms such as itching and irritation. *Shuddha Gairika* acts as

astringent and hemostatic agent, facilitating drying of lesions, reducing exudation (*Srava*), and enhancing wound contraction. Collectively, these ingredients act on key pathological components such as *Kapha-Pitta dushti*, *Rakta* involvement, and *Twak vikara*, thereby providing a comprehensive therapeutic effect in *Ahiputana*.

10.2 Comparative Assessment:

Panchavalkala ointment, used as the control intervention, is a classical formulation widely recognized for its *Kashaya* rasa predominance and established efficacy in managing inflammatory and exudative skin conditions. Its pharmacological actions primarily include *Shothahara* (anti-inflammatory), *Kledahara* (moisture-absorbing), and *Vrana Ropaka* (wound-healing) effects. The comparative evaluation in this study is expected to highlight differences in clinical efficacy, onset of action, and overall patient acceptability between the two formulations. While *Panchavalkala* ointment serves as a standard treatment, *Arjunadi* cream, owing to its modified dosage form, may offer advantages such as improved spreadability, enhanced absorption, and better compliance in pediatric patients. Furthermore, the incorporation of both subjective (FLACC and ItchyQuant scales) and objective (Diaper Dermatitis Severity Scale) outcome measures ensures a multidimensional assessment of therapeutic response. This

comparative approach is likely to provide robust clinical evidence regarding whether *Arjunadi* cream is equivalent or superior to the standard treatment, thereby contributing to evidence-based integration of *Ayurvedic* formulations in pediatric dermatological practice.

11. CLINICAL IMPLICATIONS

The findings of this study are expected to provide clinically relevant evidence for the use of *Arjunadi* cream as a safe and effective topical intervention in the management of *Ahiputana* (diaper dermatitis) in infants. If proven efficacious, it may serve as a cost-effective and well-tolerated alternative to conventional treatments, minimising the risk of adverse effects associated with prolonged use of modern topical agents. The cream formulation may enhance ease of application, absorption, and caregiver compliance in pediatric practice. Additionally, its multi-targeted action on inflammation, infection, and moisture control aligns with the multifactorial pathogenesis of the condition. The study may also support the integration of classical *Ayurvedic* formulations into routine pediatric dermatological care. Furthermore, it can guide clinicians in selecting evidence-based, child-friendly herbal therapies. Overall, this research may contribute to improving the quality of care and therapeutic outcomes in infants suffering from *Ahiputana*.

12. STRENGTHS AND LIMITATIONS

The study employs a randomized controlled design with appropriate allocation concealment, enhancing internal validity and reducing selection bias. Use of both subjective (FLACC and ItchyQuant scales) and objective (Diaper Dermatitis Severity Scale) outcome measures ensures comprehensive assessment of clinical efficacy. Standardized drug preparation and defined treatment protocols improve reproducibility. Multiple assessment time points (Day 0, 8, and 15) allow evaluation of treatment response over time. Additionally, the comparison with a standard *Ayurvedic* formulation (*Panchavalkala* ointment) strengthens the clinical relevance of findings. The study is limited by a relatively small sample size and short duration of intervention, which may affect the generalizability and long-term applicability of results. Being an open-label study, there is potential for observer and performance bias. Lack of blinding may influence subjective outcome assessment. Variability in caregiver compliance and hygiene practices could also act as confounding factors. Furthermore, microbiological evaluation and objective skin barrier assessments are not included.

13. FUTURE SCOPE

Future studies with larger sample sizes and multicentric designs are recommended to validate and generalize the findings.

Double-blind trials with longer follow-up periods can provide stronger evidence regarding sustained efficacy and safety. Incorporation of microbiological studies and skin barrier function tests may help elucidate the mechanism of action. Comparative studies with modern standard treatments can further establish clinical utility. Additionally, exploring different formulations and delivery systems of *Arjunadi* (such as gels or lotions) may enhance applicability and patient acceptability in pediatric care.

14. ACKNOWLEDGEMENTS

The authors are grateful to Parul Institute of Ayurved and Research for providing facilities and resources to enable this work.

Funding: Nil

Conflict of interest: Nil

Ethical approval: PIAyR/2026/72/IEC-PIAR HR, Dated 20/01/2026

CTRI registration: CTRI/2026/02/104596
[Registered on: 24/02/2026]

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