RESEARCH PAPER

Comparative Evaluation of Efficacy of Modified Form of Sindooradhya Taila (Ointment) and Vachadi Ointment in the Management of Scabies (Pama) in School-Going Children: A Randomized Clinical Trial

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Received: 10-07-2026; **Revised:** 20-09-2026; **Accepted:** 11-10-2026

ABSTRACT

Introduction:

In Ayurveda, Kushtaroga refers to skin diseases, including Pama Kushta, a Pitta-Kapha dominant minor disorder resembling scabies in modern medicine. Scabies is a highly contagious parasitic condition, especially prevalent in tropical regions and among children, with a 13% prevalence in rural India. *Sindooradhya taila*, an Ayurvedic herbal formulation, has shown effectiveness in treating Pama. This study aims to convert it into an ointment to improve ease of use, increase shelf life, and ensure safety for children. The ointment helps kill mites and their eggs, relieve symptoms like itching and inflammation, form a protective barrier, and prevent secondary infections. This approach blends Ayurvedic healing with modern practices for better, evidence-based treatment.

Need of Study:

The research focuses on evaluating the effectiveness of classical Ayurvedic treatments, specifically Sindooradhya Ointment, in managing Pama (scabies), a common skin disease among low socio-economic groups in rural India. The study aims to provide clinical evidence of Ayurveda's efficacy, compare it to conventional treatments, and assess safety, dosage, and cost-effectiveness—especially in children under 16.

Aim:

Comparative Evaluation of Efficacy of Modified Form of Sindooradhya Taila (Ointment) and Vachadi Ointment in the management of Scabies (Pama) in school-going children.

Materials and Methods:

This single-blind superiority clinical trial will take place over a period of one and a half years (May 2025 – Nov 2026) at Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Wardha. The study is registered under CTRI/2025/04/085290. It involves 116 patients meeting inclusion criteria, randomly assigned into two groups of 58. Group A will receive Sindooradhya ointment while Group B will receive Vachadi ointment local application twice a day for 14 days. Assessment will be conducted on 0th, 3rd and 7th day with follow-up on day 14th and 21st. Outcome will be measured using subjective and objective criteria as well as parental questionnaire.

Keywords: Sindooradhya Taila, Vachadi Ointment, Pama Kushta.

How to cite this article: *Tushar Subhash Nandanwar1* Rahul Jumle2 Renu Rathi3 Archana Pandey Jumle4. Comparative Evaluation of Efficacy of Modified Form of Sindooradhya Taila (Ointment) and Vachadi Ointment in the Management of Scabies (Pama) in School-Going Children: A Randomized Clinical Trial. Int J Drug Deliv Technol. 2026;16(87s):1579-1582. DOI: 10.25258/ijddt.16.87s.167.*

Source of support: Nil.

Conflict of interest: *None*

Key Message:

- Converting classical *Sindooradhya Taila* into an ointment improves topical stability, ease of application, and patient compliance in children.
- *Pama Kushta* (scabies) remains a significant public health challenge in rural India, particularly among pediatric populations in low socio-economic groups.
- This study evaluates a traditional *Ayurvedic* intervention against a standard *Vachadi* ointment to provide evidence-based validation for managing parasitic skin infestations.
- The research aims to establish clinical safety, dosage, and cost-effectiveness of *Ayurvedic* management for school-going children

Introduction:

In Ayurvedic medicine, *Kushtaroga* refers to dermatological disorders, categorized into seven major (*Mahakushta*) and eleven minor (*Shudra Kushta*) types. *Pama Kushta*, a *Pitta-Kapha* predominant *Shudra Kushta*, is marked by multiple small papules, serous discharge (*Strava*), pruritus (*Kandu*), and burning sensation (*Daha*). It is highly contagious and typically affects interdigital spaces and the perigenital region. Clinically, *Pama Kushta* is analogous to scabies, a parasitic skin infestation that affects approximately 130 million people globally, with higher prevalence in tropical regions and pediatric populations, particularly in rural India.

This research focuses on converting *Sindooradhya Taila*, a classical formulation described in the *Gadnigadh*, into an ointment form to improve its topical application, stability, and patient compliance—especially among children. The herbal ointment aims to exert acaricidal effects by eliminating mites and ova at the site of infestation, reducing associated symptoms such as itching, erythema, and inflammation, while forming a protective barrier to prevent reinfection and secondary complications. This formulation exemplifies an integrative approach, aligning traditional Ayurvedic therapeutics with modern pharmaceutical delivery systems to ensure efficacy, safety, and evidence-based clinical application.

AIM: Comparative Evaluation of Efficacy of Modified form of *Sindooradhya Taila* (Ointment) and *Vachadi* Ointment in the management of Scabies (Pama) in school-going children: A Randomized clinical trial

Objectives

Primary objectives:

1. To assess the efficacy of Modified form of *Sindooradhya taila* (ointment) in reliving the symptoms and improving the condition of scabies (Pama).
2. To assess the efficacy of Vachadi ointment in reliving the symptoms and improving the condition of scabies (Pama).
3. To compare the efficacy of Modified form of *Sindooradhya taila* (ointment) and Vachadi ointment in reliving the symptoms and improving the condition of scabies (Pama).

REASEARCH QUESTION

Whether Modified form of *Sindooradhya taila* (Ointment) is more efficacious
than *Vachadi* ointment for the management of scabies (*Pama*) in school-going
children?

1.Alternate Hypothesis (H1)- Modified form of *Sindooradhya taila* (ointment)
is more efficacious than *Vachadi* ointment for the management of scabies
(*Pama*) in school-going children.

2.Null Hypothesis(H0)- There is no significant difference between the efficacy
of Modified form of *Sindooradhya taila* (ointment) and *Vachadi* ointment for
the management of scabies (*Pama*) in school-going children

MATERIALS AND METHODS

Sampling Procedure:

A sampling procedure by simple randomisation by computerised generated table will be done in this randomised standard control single-blind superiority clinical trial. The research will be conducted in Wardha, Maharashtra, India's Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (H), having sample size of 60 subjects, 30 in each group. The duration of study will be from (May 2025–Nov 2026) one and a half years. The Institutional Ethical Committee (IEC) granted the ethical approval (MGACHRC/IEC/Jun-2024/826). The CTRI/2024/07/070559 registration number for the experiment is attached to it. Prior to the trial commencing, informed consent will be obtained. Fig -1 shows the study protocol's Gantt chart.

Scholar/ Investigator	Dr. Tushar Subhash Nandanwar					
Title	**"Comparative Evaluation of Efficacy of Modified form of *Sindooradhya Taila* (Ointment) and *Vachadi* Ointment in the management of Scabies (*Pama*) in school-going children: A Randomized clinical 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						■

Sample size:

Sample size calculation by comparing two proportions of overall improvement seen in assessment criteria.

Formula:

$$p = \frac{p1 + rp2}{1 + r}$$

$$n \geq \frac{\left[Z_{1-\alpha/2}\ \sqrt{(r+1)p(1-p)}\ +Z_{1-\beta}\sqrt{rp1(1-rp1)+p2(1-p2)}\right]^2}{r(p2-p1)^2}$$

Alpha (α): 0.05
Beta (β): 0.2
Proportion in group 1: 0.7168
Proportion in group 2: 0.9168
Ratio (Group 2 / Group 1): 1
Result:
Minimum sample size needed for group 1: **58**
Minimum sample size needed for group 2: **58**
Minimum total sample size needed: **116**

Inclusion Criteria:

1. Patient with age group of 5 to 16 years will be selected from *Kaumarbhritya* OPD and IPD MGACH&RC, AVBRH, peripheral OPDs and various routine health check-up camp organised by the institution.
2. Patient having classical signs and symptom of *Pama* and fulfilled the diagnostic criteria.
3. Selection of patient will be performed irrespective of sex, socio-economic status, races and community.
4. Parents willing for participation of their child in clinical trial and ready to give Written consent.

Exclusion criteria:

1. Patients with dermatological conditions that may mimic or complicate the diagnosis of scabies, such as psoriasis, eczema, or dermatitis.
2. Patients with conditions or medications that significantly impair immune function, such as HIV/AIDS, organ transplantation, or immunosuppressive therapy.
3. Patients with known allergies or sensitivities to the study medication or its compound.
4. Norwegian scabies.

Withdrawal Criteria:

1. Patient not giving proper follow up and having any adverse effect.
2. Patient whose symptom do not resolve even after 6 doses of medicine will be withdrawn.

Preparation of 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. *Sindooradhya Taila* will be prepared as per classical method in GMP- certified *Dattatraya Rasashala* as per Standard protocol and will be analyzed in pharmaceutical laboratory. Ingredients will be cleaned properly to remove the impurities. The classical Sindooradhya Taila is converted into an ointment by incorporating a suitable base (like petroleum jelly or a herbal alternative) to improve consistency and stability. It will be filled in containers & to be sealed properly

Primary Outcome:

There was a reduction in objective parameters such as the number of blackhead papules and vesicles (Shyava and Aruna Varna Pitika), along with a decrease in eosinophil count in the CBC. Subjectively, improvements were noted in the severity grading scale for crusted scabies, including reductions in pruritus (Kandu Pariah), discharge (Strava), and erythema (Raaga)

Schedule of enrolment, interventions:

Drugs will be administered twice daily for 14 days. Assessments will take place on days 0-3 and 7, with follow-ups on 14th ,21st days.

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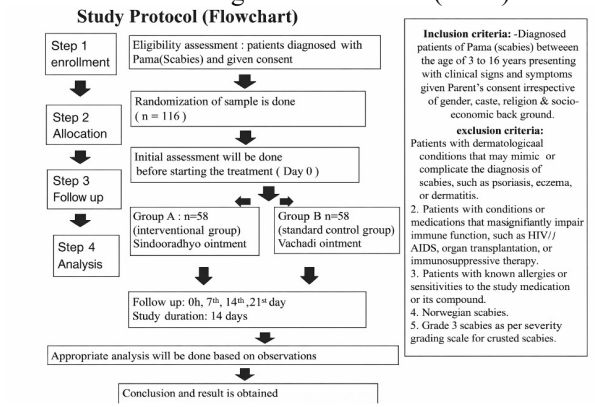
Implementation:

The subjects will be registered by principal investigator, and assessment will be done by the second investigator, there will be 2 groups, each with 58 patients. [Fig.-2].

Figure 2-Posology and Grouping

Group	**Sample size**	**Intervention**	**Dose and frequency**	**Route**	**Site**	**Duration**	**Follow up**
Group S	58	Sindoordhya Ointment	Sufficient Quantity Twice a day	Local application	Affected Area	14 days	14th ,21st day
Group V	58	Vachadi Ointment	Sufficient Quantity Twice a day	Local application	Affected Area	14 days	14th ,21st day

Fig 3- Study plan



Assesment Criteria:

Objective Criteria:

Shyava, Arunvarnapitika (black head papules vesicles)

Grade	Clinical Features
Grade 0	No black head papules, vesicles any over body
Grade 1	2-3 black head papules, vesicles present over only one part of body
Grade 2	More than 2-3 black head papules, vesicles but countable, present over more than one part of body but not reaches genital organ.
Grade 3	Uncountable black head papules, vesicles present over more than two parts of body and reaches to genital organ i.e. present all over body

Complete Blood Count / Absolute Eosinophill Count

Subjective Criteria

1. **Gradations**[20]:-

Kandu Paridaha (Pruritus)

Grade	Clinical Features
Grade 0	Absent Pruritus
Grade 1	Occasional Pruritus
Grade 2	Persistent, do not disturb routine.
Grade 3	Persistent, disturb daily routine.

Strava (Discharge):-

Grade	Clinical Features
Grade 0	Absent secretion
Grade 1	Mild occasional oozing.
Grade 2	Moderate oozing after some pressure.
Grade 3	Severe oozing without some pressure.

Raaga (Erthyma):-

Grade	Clinical Features
Grade 0	Normal skin colour
Grade 1	Faint or near to normal skin colour
Grade 2	Light reddish colour
Grade 3	Dark reddish colour

Parent Questionnaire:

Present Complaints

1. When did you first notice the skin problem? ☐ Less than 1 week ago ☐ 1–4 weeks ago ☐ More than 1 month ago
2. Symptoms observed (tick all that apply):
   ☐ Severe itching (especially at night)
   ☐ Redness of skin
   ☐ Small blisters or pustules
   ☐ Crusting or scaling
   ☐ Oozing fluid
   ☐ Thickened skin
   ☐ Others (specify): _____
3. Areas affected (mark on diagram or list): ☐ Hands ☐ Between fingers ☐ Wrists ☐ Elbows ☐ Armpits ☐ Waist ☐ Buttocks ☐ Genital region ☐ Feet ☐ Other: _____
4. Has itching spread to other family members? ☐ Yes ☐ No
5. Any seasonal variation?
   ☐ Worse in summer
   ☐ Worse in winter
   ☐ No change

History

1. Past history of similar skin problems in child? ☐ Yes ☐ No
2. History of similar complaints in siblings? ☐ Yes ☐ No
3. Any history of skin disease in parents or grandparents? ☐ Yes ☐ No
4. Recent contact with affected person/animal? ☐ Yes ☐ No
5. Recent change in soaps, detergents, or clothing? ☐ Yes ☐ No
6. Use of any skin ointment/medicine before consultation? ☐ Yes ☐ No (If yes, specify: _____)

Lifestyle & Hygiene Factors (Ayurveda Perspective)

1. Bathing frequency: ☐ Daily ☐ Alternate days ☐ Occasionally
2. Type of bathing water: ☐ Cold ☐ Lukewarm ☐ Hot
3. Soap/cleansing agent used: _____
4. Clothing habit: ☐ Cotton ☐ Synthetic ☐ Mixed

5. Sharing of clothes/towels with others: ☐ Yes ☐ No
6. Sleeping arrangement: ☐ Separate bed ☐ Shared bed ☐ Floor mattress
7. Diet pattern:
8. Excessive intake of: ☐ Curd ☐ Sour foods ☐ Oily/fried foods ☐ Junk food
9. Regular intake of fruits & vegetables: ☐ Yes ☐ No
10. Water intake (per day): _____ litres

Data management: Data coding will be handled by the principal investigator.

Consent or assent: Prior to the study's commencement, the patient's written consent will be obtained. Every patient's confidentiality will be upheld throughout the investigation.

Dissemination policy: Publication of papers will be used to spread the data. The qualifying criteria for authors and the planned usage of expert writers

Informed consent: Informed written consent will be taken from each participant.

STATISTICAL ANALYSIS:

The data will be analyzed by using an appropriate statistical test.

(ex. paired t-test & unpaired t-test for objective parameters and Wilcoxon signed rank test and
Wilcoxon rank sum test, one/ two way FPS-R tests for subjective parameters.)

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