

Original Research Article

Evaluation of safety and efficacy of prickly heat baby powder in 0-36 months babies

Mohit Poddar¹, Sachin Bhargava², Mukund Sangamnerkar³, Rajesh Kumawat^{4*}

¹Department of Pediatric, NIMS Medical College, Jaipur, Rajasthan, India

²Dr. Bhargava Clinic, Ghaziabad, Uttar Pradesh, India

³Department Chinmay Institute of Pediatrics, Pune, Maharashtra, India

⁴Medical Services and Clinical Development, Himalaya Wellness Company, Bengaluru, Karnataka, India

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*Correspondence:

Dr. Rajesh Kumawat,

E-mail: rajesh.kumawat@himalayawellness.com

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ABSTRACT

Background: Given the unique sensitivity of baby skin, this study emphasizes the importance of effective skincare products that cater to the delicate nature of young children's skin. This study was conducted to evaluate the safety, tolerability and efficacy of "Prickly Heat Baby Powder," a polyherbal formulation designed to alleviate symptoms associated with prickly heat in infants and toddlers.

Methods: This was an open-label, single-arm, multicentric study was conducted across 24 medical facilities in India, the trial involved 500 healthy full-term newborns, infants and toddlers aged 0–36 months. Over a 15 (+1) day period, parents/LAR were instructed to apply the powder after bath and nappy changes.

Results: The study assessed product tolerability and efficacy through paediatric evaluations and subjective feedback from parents. Results indicated that 68.6% of subjects experienced significant symptom resolution, with the product rated as mild and gentle for infant skin. No adverse effects were reported and a high acceptance rate was noted among subjects.

Conclusions: The formulation's natural ingredients, including Yashada bhasma, Neem, Karanja and Khus Khus, were highlighted for their antiseptic and anti-inflammatory properties, making it a safe alternative to conventional products. This study supports the potential of herbal formulations in paediatric dermatology and suggest that "Prickly Heat Baby Powder" effectively addresses the discomfort associated with prickly heat, aligning with the growing consumer preference for natural skin care solutions for children.

Keywords: Baby powder, Gentle, Infants, Mild, Prickly heat

INTRODUCTION

A baby's skin is delicate and sensitive in nature, significantly differing from adult skin in both structure and function. Understanding these differences is crucial for effective care during the early stages of life. A child's skin undergoes significant maturation and development, adapting from the delicate nature of infant skin to a more resilient form. Skin maturation begins at birth and continues throughout the first few years of life. By the

end of the first year, infant skin starts to resemble adult skin more closely, with structural and functional improvements occurring continuously.^{1,2} The stratum corneum (SC) thickens and the epidermis becomes more organized, leading to better barrier function and reduced trans epidermal water loss (TEWL) over time. Due to smaller corneocytes, wider spaces between corneocytes, a thinner stratum corneum, fewer normal microflora and lower skin lipid, newborn skin is more susceptible to dryness than adult skin.³⁻⁵ Excessively dry skin can cause

infection and damage to the skin barrier. Prickly heat, also known as heat rash or miliaria, is a common dermatological condition characterized by small, itchy red bumps and arises when sweat glands become blocked, leading to inflammation and discomfort. This condition is particularly prevalent during hot and humid weather, where babies are more susceptible to excessive sweating.⁶ The primary symptom of prickly heat is intense itching, which can cause significant discomfort for infants and toddlers. This constant itching often leads to irritability and fussiness, making it difficult for caregivers to soothe them. The discomfort from the rash also interferes with their sleep patterns.

Babies may wake frequently due to the itching sensation, leading to fatigue for both the child and the parents. The persistent discomfort can result in behavioural changes, such as increased restlessness or difficulty engaging in play, which are crucial for a child's development. Its symptoms can significantly diminish the quality of life for newborns and toddlers through physical discomfort, emotional distress and social implications. Effective management strategies are essential to mitigate these effects.

The delicate skin of infants requires special care to prevent and alleviate the symptoms associated with prickly heat, making effective skincare products essential for maintaining their comfort. The chances of contracting these symptoms in infants and children is comparatively higher due to their less mature barrier function and sweat ducts which may also lead to heat rashes.⁷ Consequently, topical products for infants should be carefully formulated such that preparations should minimize the use of irritating/sensitizing ingredients.

Using safe and well-tolerated natural infant care products is essential to protecting the skin barrier of newborns and toddlers, who are frequently exposed to a variety of external factors. This explains the growing demand for natural ingredient-based products among consumers and medical experts. The “Prickly heat Baby Powder” is a polyherbal formulation recommended for reduction and prevention of rashes and itching to the baby’s skin and it contains the oils of *Santalum album*, *Vetiveria zizanioides* and *Olea europaea* and the powder of *Yashada bhasma*.

To confirm non-allergenic potential of prickly heat powder, it was evaluated through HRIPT on 200 adults (male/female) healthy volunteers as a standard development process of topical products (BIS4011:2018 guidelines).⁸ The results of a study evaluating the safety and efficacy of prickly heat baby powder for newborns, babies and toddlers are presented in this article.

METHODS

Study design

This was an open label, single arm, multicentric study conducted to assess the tolerability, safety and

effectiveness of Prickly heat baby powder after use for 15 days period. This study included 500 subjects (N) and parents were instructed to sprinkle the test product on to their palms and apply on baby’s skin after bath, nappy changes and before bed-time.

24 distinct medical facilities (out-patient clinics/hospitals) around India were included in this multicentric study, ensuring a wide geographic distribution and eliminating the contingency of bias (1. Poddar Hospital, Jaipur 2. Shrivnath Children Hospital, Vadodara 3. GSVM Medical College, Kanpur; 4. Chinmay Institute of Pediatrics, Pune 5. Mediclin Polyclinic and Pharmacy, Bhubaneswar 6. Dr. Bhargava Clinic, Ghaziabad 7. Sparsh Child Care and Gastro Centre, Lucknow 8. Jai Clinic, Ajmer 9. Shourya Childcare and Maternity Clinic, Bhopal 10. Citizen Hospital, Bangalore 11. Mangal Murti Children's Clinic, Pune 12. Dr. Agarwal's Clinic, Noida 13. B D Pathak Hospital, Rudrapur. 14. Brij Medical Centre, Kanpur; 15. Atmaram Child Care Hospital, Kanpur 16. Dr. V D Patil Patil Clinic, Belagavi 17. Navjot Eye and Children Clinic, Belagavi 18. Khalatkar Hospital, Nagpur 19. Shivam Children Hospital and Neonatal Care Centre, Ahmedabad 20. Pal Clinic, Howrah; 21. Dimension Medicare Centre, Kolkata; 22. Alliance Healthcare, Guwahati 23. Navkaar Clinic, Mumbai 24. FS Endocrine and Diabetic Centre, Telangana). The study lasted for a period of 15(+1-day Window period) days, beginning from Apr-2022 to Jul-2022.

Study subjects

Full-term newborns, infants and toddlers of age 0–36 months of either sex with one or more symptoms of prickly heat such as itching, redness and rashes due to friction (in elbows, arms and knees etc) were considered eligible for this study. Subjects were required to be in overall good health, as confirmed through pediatricians by recent medical history and physical examination. Subjects with a documented history of allergies requiring medical intervention, with a history of allergy to any of the components of the test products or those currently experiencing allergic conditions, as well as individuals with chronic illnesses were excluded from the study. Additionally, subjects whose parents or guardians were unwilling to halt the application of concomitant similar products throughout the study, were also excluded. A written informed consent was obtained from the subjects’ parent /LAR (Legally Authorized Representative).

Intervention/study product

The parents were instructed to sprinkle ‘Prickly Heat Baby powder’ on to their palms and apply on baby’s skin (all over the body) after bath and whenever necessary for a period of 2 weeks. Parents were given a caution to avoid using it around baby’s eyes, nose, mouth and sensitive areas and not to sprinkle directly onto baby’s skin to avoid accidental inhalation. They were asked to

discontinue the product, if they noticed any adverse effect. This study encompassed of two distinct visits: The initial visit, denoted as the screening, enrolment and test product application (Visit 1). The final assessment, known as end of study (EOS) Visit (Visit 2), took place on day 15±1.

Ethical conduct of the study

Before commencing the descriptive study, it underwent review and approval by Ethics committee (The Raneshwar Multispecialty Hospital Ethics Committee; Reg. No. ECR/1232/Inst/GJ/2019, approved on 20/08/2022) and in accordance with all applicable regulations ensuring that the rights, safety and welfare of trial subjects are prioritized, ICH-GCP (International council for harmonization of technical requirements for pharmaceuticals for human use-good clinical practice) requirements, Indian drug cosmetic act 1940, ICMR Guidelines and Declaration of Helsinki.⁹ This study was prospectively registered in Clinical Trials Registry of India (CTRI/2021/10/037163).

Safety and Efficacy Assessments

Safety was evaluated by paediatricians through the assessment of local intolerance, including symptoms like dryness, erythema, edema, scaling, itching, rashes and burning sensation. Any undesirable event was monitored and documented in accordance with COLIPA guidelines for adverse events (AE) and serious adverse events (SAE).¹⁰

Efficacy assessments included the dermatological evaluation of mildness and gentleness of the product on baby's skin. This was assessed by pediatricians in every study visit. A Subjective assessment was recorded on Visit 1 (Baseline/ Day 1) and Visit 2 (EOS/Day 15+1) to appraise the overall suitability of the test product with respect to keeping the baby's skin soft and smooth. The scoring provided by the subject's parent/ LAR and was in turn correlated with response to the treatment. Additionally, symptom assessment questionnaire was filled by Subject's parent / LAR at Visit 1 (Baseline/ Day 1) and Visit 2 (EOS/ Day 15) to assess the product's efficacy in resolving the existing symptoms (rashes, itchiness etc). Moreover, at the end of the study, a subjective feedback questionnaire was used to capture the parents' experiences with test product and gathering insights about the product from the perspective of users.

Statistical analysis

The subjects' demographic details were analysed using descriptive statistics. Central tendencies, measures of dispersion, frequencies and percentages were used to summarize quantitative variables. To assess the significance of continuous variables, Wilcoxon matched pairs signed rank test was utilized, level of significance

was fixed at a level of 0.05. Statistical analyses were conducted by GraphPad Prism version 6.07.

RESULTS

Demographic distribution of subjects

The demographic details, including age and gender, for each subject are shown in Table 1. Children of three different age groups were included in the study: 0 days to ≤1 month, 1 month to ≤12 months, 12 months to 36 months. In this study, 52.4% of the subjects were female and 47.6% were male maintaining equitable gender ratio.

Dermatological assessment

Dermatological Assessment in terms of frequency and percentage indicated that the test product was mild and gentle for infants' skin in over 90% of subjects, the test product was rated as good, very good and excellent in terms of parameters like mildness and gentleness. The responses were recorded by the Pediatricians at the End of Study. The details are given in Figure 1, Figure 2 and Table 2.

Subjective assessment questionnaire

The subjects' parents/LAR completed subjective assessment questionnaires at the baseline and at the End of Study (EOS) (Details given in Table 3). The outcome was assessed based on 0-to-10-point scale for each question, Q1: 0=Not Soft 10=Very Soft, Q2: 0=Very rough 10=Very smooth. By EOS, 46.6 % of the subjects showed improvement in softness and 40.7% of the subjects showed improvement in smoothness of the skin demonstrating notable clinical validation of the prickly heat baby powder.

Symptom assessment questionnaire

Symptom assessment questionnaire was used to assess the effect of the test product in resolving the existing symptoms (rashes, itchiness etc) after use for 15 days. When compared to baseline, there was a significant reduction in rash and itchiness at EOS (Table 4) The Prickly heat powder resolved the prevailing symptoms in 68.6% of subjects (Table 5). Results indicated that the subjects had their symptoms resolved in 10 median days. The minimum number of days necessary for symptom resolution was 3, while the maximum number of days required was 16 (Table 6).

Subjective feedback for the product

At the end of the study, a subjective feedback questionnaire was used to capture the parents' experiences with test product and gathering insights about the product from the perspective of users. After using the Prickly Heat Baby Powder for 15 days, 91% to 98% of the subjects' parents /LAR expressed their

acceptance by agreeing that the Prickly heat baby powder helps to relieve skin rashes, soothe and calm the irritated and red skin, relieve itching of baby's skin from prickly heat (Details given in Table 7). The subject's parents/LAR also appraised that the test product keeps baby's skin cool, soft, moist-free and helps reduce the effects of rubbing and friction of baby's skin. The fragrance of the Prickly heat baby powder was mild and its usage improved the overall condition of baby's skin. Almost all subject's parents/ LAR accepted that they felt good after using Himalaya prickly heat baby powder.

Adverse events and local intolerance

None of the subject had any adverse effects during the entire course of the study. All the subjects displayed an adequate acceptance to Prickly Heat Baby Powder. No worsening of dry skin was observed in any of the subject during the course of the trial. None of the parents/LAR of the subjects complained of any side effects or untoward reactions.

Table 1: Demographic distribution of subjects.

Parameters	Statistics	n=500
Gender (%)	Female	262 (52.4)
	Male	238 (47.6)
Age (in months)	Mean	14.7
	Standard deviation	9.79
	Min	0.0
	Max	35.4
	Median	12.9

Table 2: Summary of dermatological assessment for mildness and gentleness (n=500).

Parameters	Response	n=500 N (%)
Mildness of prickly heat baby powder on baby(s) skin	0: Nil	1 (0.2)
	1: Fair	34 (6.8)
	2: Good	128 (25.6)
	3: Very good	225 (45.0)
	4: Excellent	112 (22.4)
Gentleness of prickly heat baby powder on baby(s) skin	0: Nil	2 (0.4)
	1: Fair	29 (5.8)
	2: Good	134 (26.8)
	3: Very good	205 (41.0)
	4: Excellent	130 (26.0)

Table 3: Summary of subjective assessment for softness and smoothness.

Questionnaire	Statistics	Baseline	Day 15/ EOS	CFB	%CFB
	N	500	500	500	500
How soft is you baby(s) skin?	Mean±Sd	5.6±1.41	7.7±1.11	2.1±1.31	46.6
How smooth is your baby(s) skin?	Mean±Sd	5.7±1.29	7.7±1.2	2±1.21	40.7
P value			*p<0.0001		

*Statistical test: paired t test/ Wilcoxon matched pairs signed rank test, level of significance was fixed at 0.05, CFB: Change from Baseline. Sd: Standard deviation.

Table 4: Symptom assessment questionnaire (responses by subject's parents/ LARs).

Questionnaire	Statistics	Baseline	Day 15/ EOS	CFB	%CFB
	N	500	500	500	500
Q1: Does your baby have skin itchiness?	Mean±Sd	6.8±1.49	9.4±1.12*	2.6±1.39	43.2
Q2: Does your baby have red patches / redness on skin?	Mean±Sd	7±1.43	9.5±1.02*	2.4±1.33	39.4
Q3: Does your baby have skin rashes due to friction (in elbows, arms and knees etc)?	Mean±Sd	7.9±1.63	9.7±0.81*	1.8±1.41	27.8
Q4: Does your baby have boils / blister?	Mean±Sd	9.7±0.88	10±0.32*	0.2±0.76	3.4
Q5: Does your baby have burning sensation?	Mean±Sd	8.4±1.7	9.7±0.87*	1.3±1.46	19.9
P value			*p<0.0001		

*Assessed on 0-to-10-point scale, Q1: 0=Very itchy skin 10=No itching, Q2: 0=Severe red patches 10=No red patches, Q3: 0=Severe rashes 10=No rashes, Q4: 0=Many boils / blister 10=No rashes boils / blister, Q5: 0=Severe burning 10=No burning, Statistical test: Paired t test/ Wilcoxon matched-pairs signed rank test, level of significance was fixed at 0.05, CFB: Change from Baseline. Sd: Standard deviation.

Table 5: Summary of symptom resolution.

Question	Visit	Response	N (%)
Does your baby have prickly heat symptoms?	Baseline	Yes	500 (100)
		No	0 (0)
Did the symptoms get resolved? (prickly heat)	Day 15/ EOS	Yes	343 (68.6)
		No	157 (31.4)

EOS= End of Study

Table 6: Summary of duration of symptom resolution (days).

Parameter	Variables	
Symptoms resolved (in days)	N	343
	Median	10.0
	Min, Max	3,16

Min = Minimum, Max = Maximum, N: number of Subjects

Table 7: Summary of subjective feedback of the product (n=500).

Questionnaire	Response	N (%)
1. Prickly heat baby powder helps heals rashes on your baby(s) skin.	1=Strongly disagree	0
	2=Disagree	0
	3=Neither agree nor disagree	26 (5.2)
	4=Agree	314 (62.8)
	5=Strongly agree	160 (32.0)
2. Prickly heat baby powder calms and soothes your baby(s) skin.	1=Strongly disagree	0
	2=Disagree	0
	3=Neither agree nor disagree	23 (4.6)
	4=Agree	328 (65.6)
	5=Strongly agree	149 (29.8)
3. Prickly heat baby powder helps soothe red and irritated skin of your baby.	1=Strongly disagree	0
	2=Disagree	2 (0.4)
	3=Neither agree nor disagree	32 (6.4)
	4=Agree	309 (61.8)
	5=Strongly agree	157 (31.4)
4. Prickly heat baby powder helps relieving skin rashes on your baby(s) skin.	1=Strongly disagree	0
	2=Disagree	3 (0.6)
	3=Neither agree nor disagree	21 (4.2)
	4=Agree	270 (54.0)
	5=Strongly agree	206 (41.2)
5. Prickly heat baby powder helps relieving itching due to prickly heat on your baby(s) skin.	1=Strongly disagree	0
	2=Disagree	4 (0.8)
	3=Neither agree nor disagree	14 (2.8)
	4=Agree	302 (60.4)
	5=Strongly agree	180 (36.0)
6. Prickly heat baby powder keeps your baby(s) skin cool and soft.	1=Strongly disagree	0
	2=Disagree	1 (0.2)
	3=Neither agree nor disagree	43 (8.6)
	4=Agree	245 (49.0)
	5=Strongly agree	211 (42.2)
7. Prickly heat baby powder keeps your baby(s) skin soft and moist-free.	1=Strongly disagree	0
	2=Disagree	0
	3=Neither agree nor disagree	27 (5.4)
	4=Agree	296 (59.2)
	5=Strongly agree	177 (35.4)
8. Prickly heat baby powder helps reduce the effects of rubbing and friction of your baby(s) skin.	1=Strongly disagree	2 (0.4)
	2=Disagree	1 (0.2)
	3=Neither agree nor disagree	37 (7.4)
	4=Agree	282 (56.4)
	5=Strongly agree	178 (35.6)

Continued.

Questionnaire	Response	N (%)
9. Fragrance of Prickly heat baby powder is mild.	1=Strongly disagree	0
	2=Disagree	2 (0.4)
	3=Neither agree nor disagree	22 (4.4)
	4=Agree	269 (53.8)
	5=Strongly agree	207 (41.4)
10. Prickly heat baby powder improved the overall condition of your baby(s) skin.	1=Strongly disagree	0
	2=Disagree	3 (0.6)
	3=Neither agree nor disagree	12 (2.4)
	4=Agree	287 (57.4)
	5=Strongly agree	198 (39.6)
11. You feel good using Himalaya Prickly heat baby powder.	1=Strongly disagree	0
	2=Disagree	2 (0.4)
	3=Neither agree nor disagree	6 (1.2)
	4=Agree	231 (46.2)
	5=Strongly agree	261 (52.2)

DISCUSSION

This observational study has certain credentials like, this is a multicentric study, spanning over 24 pediatric centres across India with inclusion of 500 children of 0-36 months age group, adhered to high standards of clinical research, including registration with CTRI, approval by CDSCO registered Ethics Committee and adherence to ICH-GCP guidelines. Gender balance was maintained, enrolling roughly equal proportions of male and female infants, mitigating potential gender-based variations in outcomes.

The safety and effectiveness of the test product was evaluated in children from 0 to 36 months with at least one or more symptoms of prickly heat such as itching, redness and rashes due to friction (in elbows, arms and knees etc). The results of our study indicate that the test product was effective in resolving the symptoms and improving soothing and smoothing effect and feel of coolness on children's skin.

The product has astringent properties that treat the rash and provides quick relief by alleviating inflammation and easing itchy sensation. The product also helped reduce child's restlessness by providing an instant soothing action, while protecting the skin from further outbreaks and infections.

For many decades herbal medicinal products have been used for children's health care.¹¹ Many natural molecules of plant origin, such as alkaloids, flavonoids, isoflavones, proanthocyanidins, phenolic compounds and essential oils, are associated with the treatment of many dermatological conditions.¹²

Himalaya Prickly Heat Baby Powder is formulated with natural ingredients like Yashada bhasma, Neem (*Azadirachta indica*), Karanja (*Pongamia pinnata*) and Khus Khus (*Vetiveria zizanioides*). Yashada Bhasma, a Zn based herbo-metallic preparation, is reported to possess significant antiseptic and anti-inflammatory properties and hence used in the management of various

skin conditions including wound healing as it effectively soothes irritated skin rashes.¹³ The antibacterial, anti-inflammatory, antifungal and antiviral properties of neem's active ingredients such as nimbidin, nimbin and nimbidol promote wound healing. In addition, neem contains high concentrations of minerals, vitamins and amino acids that are essential for wound healing during the proliferative phase.¹⁴

Neem oil is beneficial in managing itching, rashes and inflammation and its antioxidant property provides protection to baby's skin.^{15,16} Karanja is reported to possess significant antibacterial activity against skin pathogens. The emollient property of oil moisturizes and soothes the baby's skin. The anti-microbial and anti-inflammatory properties helps relieve itching and wound healing property effectively heals rashes.¹⁷

The oil of the herb *Vetiveri zizanioides* is reported to possess astringent, antimicrobial and antiseptic activity. It is useful in skin care, as a tonic and detoxifier.¹⁸ It also plays a pivotal role in providing symptomatic relief and preventing further outbreaks.

In addition, Prickly heat baby powder is free from parabens, phthalates, talc and synthetic colors that may pose the greatest risk linked to skin damage and even cancer and therefore considered a safer recommendation for infants and children.¹⁹

This contrasts with some other brands that have faced criticism for causing rashes or discomfort upon application due to harsh chemicals or fragrances. Although study findings seem encouraging, it also had certain limitations.

Firstly, the study was open label which increases the chance of discriminatory disclosure leading to bias. The difficulty in designing a blinded study is recognized as a design limitation. Since the study had no objective parameter and comprised of only subjective assessments, lead to the possibility of reporting bias. In further investigations, objective assessments including clinical

parameters, instruments and comparative photographs could be considered, resulting in more accurate, impartial and quantitative outcomes. As parents increasingly seek safe and effective solutions for their children's skincare needs, products like prickly heat baby powder will likely continue to gain traction.

The emphasis on natural ingredients not only aligns with contemporary consumer preferences but also addresses health concerns associated with synthetic alternatives. Formulated with herbal ingredients, the test product is proven safe and effective with no adverse events.

CONCLUSION

Through this clinical study prickly heat baby powder has been verified for its safety, tolerability and effectiveness for newborns and infants. Mothers/Caretakers noted the effectiveness of the product in resolving the prickly heat symptoms and study also validates the products' mild and gentle nature, ensuring to provide full care to the baby's delicate skin. For parents looking for a reliable solution to manage prickly heat during hot weather, Prickly Heat Baby Powder offers a reliable option that combines tradition with advance knowledge in the area to prove its safety and efficacy.

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Conflict of interest: Dr Rajesh Kumawat is an employee of Himalaya Wellness Company.

Ethical approval: The study was approved by the Institutional Ethics Committee (The Raneshwar Multispecialty Hospital Ethics Committee)

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