ORIGINAL ARTICLE e-ISSN: 2349-0659 p-ISSN; 2350-0964

Efficacy and Tolerability of Nixoderm Tin in the Management of Atopic Dermatitis: An Open-Label, Comparator-Controlled Clinical Study

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Abstract

Background: Topical formulations combining salicylic acid, benzoic acid, and precipitated sulfur have been reported to support the management of atopic dermatitis (AD)/eczema by aiding skin exfoliation, reducing microbial load, and easing inflammation. **Aims:** The aim of the study is to evaluate the efficacy and tolerability of Nixoderm Tin, applied twice daily, in subjects with AD, compared with a control arm. **Materials and Methods:** An open-label, parallel-group study was conducted at a single center following ethics committee approval. Forty subjects diagnosed with AD per Hanifin-Rajka criteria were enrolled (Group A: Nixoderm Tin, $n = 20$; Group B: Control, $n = 20$) and assessed at day 0, 7, 15, and 30 using the eczema area and severity index (EASI) and AD severity index (ADSI), alongside a structured patient-feedback questionnaire. **Results:** Group A showed statistically significant reductions in EASI and ADSI scores from baseline to day 30 in both full analysis set (FAS) and per-protocol set (PPS) analyses, while Group B showed slight improvement in EASI and ADSI. Between-group differences were statistically significant (EASI PPS day 30, $P = 0.0003$; ADSI FAS day 30, $P < 0.0001$). No adverse events were reported in either arm. Patient-reported improvement in Group A rose to 80% by day 30. **Conclusion:** Nixoderm Tin demonstrated significant and well-tolerated improvement in AD severity over 30 days relative to control, supporting its potential role as a topical therapy for mild-to-moderate AD.

Keywords: Atopic dermatitis, Atopic dermatitis severity index, Eczema area and severity index, Nixoderm tin, Open-label study, Topical therapy

Asian Pac. J. Health Sci., (2026); DOI: 10.21276/apjhs.2026.13.4.02

Introduction

Atopic dermatitis (AD) is a common, chronic, relapsing inflammatory skin disorder characterized by pruritic skin lesions and elevated inflammatory markers.[1] In developed countries, AD is estimated to affect 15–30% of children and 2–10% of adults, and its prevalence has increased two- to three-fold worldwide over the last three decades.[1-4] AD is frequently associated with a family history of other atopic disorders such as allergic rhinitis or asthma, and its clinical presentation varies with age, ranging from an erythematous papular rash in infancy to more diffuse, thickened, and excoriated lesions in later childhood and adulthood.[1,5,6]

Topical corticosteroids remain the cornerstone of AD management, but their use is limited by local adverse effects such as skin thinning, striae, and telangiectasia, as well as the risk of systemic absorption with prolonged use.[1,7-9] Topical calcineurin inhibitors offer an alternative with a more favorable long-term safety profile but are associated with transient local irritation.[1,7-9] Given these limitations, there remains a clinical need for well-tolerated topical formulations that can reduce AD severity without the cumulative risks associated with prolonged corticosteroid use.

Topical formulations combining salicylic acid, benzoic acid, and precipitated sulfur have demonstrated beneficial effects in managing AD/eczema by helping to exfoliate the skin, reduce microbial load, and relieve inflammation, thereby supporting skin-barrier function.[8-11] The present study was undertaken to evaluate the efficacy and tolerability of one such formulation, Nixoderm Tin, in subjects with AD, using validated clinical severity indices and a structured patient-feedback questionnaire, compared against a control arm.

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How to cite this article: Hosthota A, Sridhar S, Thejeswi RS, Jayanthi CR, Deepa K, Horti LK. Efficacy and Tolerability of Nixoderm Tin in the Management of Atopic Dermatitis: An Open-Label, Comparator-Controlled Clinical Study. Asian Pac. J. Health Sci., 2026;13(4):5-8.

Source of support: Nil.

Conflicts of interest: None.

Received: 11/05/2026 **Revised:** 28/06/2026 **Accepted:** 18/07/2026

Materials And Methods

Study Design

This was a prospective, open-label, parallel-group, comparator-controlled clinical study conducted at a single center – The Oxford Medical College, Hospital and Research Centre, Bengaluru and was approved by the Institutional Ethics Committee before commencement, and written informed consent was obtained from all participants before enrolment.

Study Population

A total of 45 subjects were screened, of whom 40 met the inclusion/exclusion criteria and were enrolled (5 screen failures). Subjects were allocated to two parallel groups of 20 each: Group A received Nixoderm Tin, and Group B served as the control. Two subjects (Subject 15 and Subject 39) discontinued during Visit 3 (day 15);

the full analysis set (FAS) comprised all 40 enrolled subjects, and the per-protocol set (PPS) excluded the two discontinued subjects and any other protocol deviators.

Eligibility Criteria

Inclusion criteria

Subjects of either sex, aged above 18 years, diagnosed with AD per Hanifin and Rajka clinical criteria[2] (≥3 of 4 major and ≥3 of 23 minor features), willing to provide informed consent, willing to complete study assessments and questionnaires, and willing to avoid other skin-care products for AD for at least 1 week before and throughout the study.

Exclusion criteria

Pregnancy or breastfeeding; other inflammatory or infective skin conditions; history of hypersensitivity to skin-care products; history of mild-to-severe anaphylaxis; pre-existing severe systemic disease requiring long-term medication; history of cancer, including solid tumors, hematologic malignancies, and carcinoma *in situ*; and participation in another clinical trial of an approved or investigational product within the preceding month.

Investigational Product and Dosing

Group A received Nixoderm Tin, applied twice daily to affected areas of AD. Group B received the designated control regimen. Investigational products were dispensed at the baseline visit, and unused product was returned at the final visit.

Study Assessments

Subjects were assessed at Visit 1 (Screening/day 0), Visit 2 (day 7, telephonic), Visit 3 (day 15), and Visit 4 (day 30). At baseline, demographic data, family history, and disease duration were recorded, and a comprehensive dermatological examination was performed. AD severity was assessed using the eczema area and severity index (EASI),[3] which evaluates lesion morphology (erythema, papules, excoriation, lichenification) and affected body-surface area and the AD severity index (ADSI). Standardized clinical photographs were taken at each visit. Safety assessments – medical and medication history, treatment history, physical examination, and assessment of comorbid conditions – were completed at baseline for all participants. Patient-reported outcomes were captured via a structured product efficacy questionnaire and patient global impression of benefit-risk assessment at days 7, 15, and 30, covering perceived safety, noticeable symptom change, perceived benefit, and overall effectiveness. Adverse events were monitored and documented throughout the study.

Statistical Analysis

A statistical analysis plan was adopted as applicable, and descriptive statistical analysis was performed. For normally distributed data, parametric tests were applied; continuous measurements are presented as mean ± standard deviation and categorical measurements as proportions. Subject feedback questionnaires were analyzed by frequency procedure and are presented as percentages. Both FAS and PPS analyses were performed for the efficacy endpoints.

Results

Subject Disposition

Of 45 subjects screened, 40 were enrolled (20 per group). Two subjects discontinued during Visit 3 (day 15). The FAS comprised 40 subjects; the PPS excluded the two discontinued subjects and any other protocol deviators.

Baseline Characteristics

Demographic characteristics assessed at Visit 1 were comparable between Group A and Group B in terms of height, weight, and body mass index, with no statistically significant between-group differences. Vital signs (temperature, heart rate, pulse rate, respiratory rate, systolic and diastolic blood pressure) were within normal limits in both groups at baseline. No significant medical history or active comorbid conditions were observed; physical examination findings were within normal limits for all subjects, and no concomitant medications were reported during the study.

Efficacy Outcomes – EASI

At baseline, the mean EASI scores were comparable between Group A (5.14 ± 0.57) and Group B (4.96 ± 0.46), with no statistically significant difference ($P = 0.2961$). By day 15, Group A showed a reduction in EASI score to 4.65 ± 0.30, while Group B remained relatively stable at 4.88 ± 0.42. By day 30, a further reduction was observed in Group A (4.52 ± 0.37), whereas Group B showed a slight increase in score (5.03 ± 0.41). The between-group difference at day 30 was statistically significant ($P = 0.0003$), indicating better improvement in EASI scores in Group A [Table 1].

Efficacy Outcomes – ADSI

Both groups had comparable baseline ADSI scores, with no statistically significant difference between the groups (FAS: Not significant; PPS: $P = 0.4706$). By day 15, Group A showed improvement in symptoms, with the ADSI score decreasing from 11.05 ± 1.54 at baseline to 10.05 ± 1.10, whereas Group B showed scores slightly increasing from 10.75 ± 1.21 to 11.40 ± 1.14. This trend continued through day 30, when the ADSI score decreased further to 9.20 ± 1.11 in Group A but increased to 12.20 ± 1.32 in Group B in the FAS. In the PPS, the day 30 scores were 9.20 ± 1.11 in Group A and 12.39 ± 1.14 in Group B. The between-group difference at day 30 was statistically significant (FAS $P < 0.0001$; PPS $P < 0.0001$). The within-group change from baseline to day 30 was significant in both groups but in opposite directions, favoring Group A [Table 2].

Table 1: Eczema area and severity index scores – per-protocol set analysis

Time point	*Group A (Nixoderm tin)*	*Group B (control)*	*P-value*
Baseline (day 0)	5.14±0.57	4.96±0.46	0.2961
Day 15	4.65±0.30	4.88±0.42	—
Day 30	4.52±0.37	5.03±0.41	0.0003

Table 2: ADSI Scores – FAS and PPS

Time point	*Group A – FAS*	*Group B – FAS*	*Group A – PPS*	*Group B – PPS*
Baseline (day 0)	11.05±1.54	10.75±1.21	11.05±1.54	10.72±1.23
Day 15	10.05±1.10	11.40±1.14	—	—
Day 30	9.20±1.11	12.20±1.32	9.20±1.11	12.39±1.14

ADSI: Atopic dermatitis severity index, FAS: Full analysis set, PPS: Per-protocol set

Table 3: Perceived noticeable improvement in atopic dermatitis symptoms

Response	*Day 7 (%)*	*Day 15 (%)*	*Day 30 (%)*
Group A – Yes (improved)	30	50	80
Group B (improved)	10	15	30

Patient-Reported Outcomes

The proportion of participants reporting noticeable improvement increased progressively over the 30-day observation period in both groups. In Group A, perceived improvement increased from 30% on day 7 to 50% on day 15 and 80% on day 30, indicating consistent improvement over time. In Group B, improvement was reported by 10%, 15%, and 30% of participants on days 7, 15, and 30, respectively. Overall, Group A showed a greater and more sustained perception of symptom improvement compared with Group B [Table 3].

Safety Outcomes

No adverse events or safety concerns were noted throughout the trial duration in either group.

Discussion

In this open-label, comparator-controlled study, Nixoderm Tin produced statistically significant and clinically consistent improvements in both EASI and ADSI scores over 30 days, with between-group differences favoring the active treatment arm across both FAS and PPS analyses. In contrast, the control arm showed slight improvement in EASI and ADSI over the same period, suggesting that the observed benefit in Group A reflects a genuine treatment effect rather than the natural course of the condition over the study period.

These clinician-assessed findings were corroborated by patient-reported outcomes: An increasing proportion of Group A participants reported noticeable improvement and perceived benefit over time, reaching 80% reporting improvement while Group B participants increasingly rated their regimen as ineffective. Notably, no adverse events were reported in either arm, and all participants in both groups consistently rated their assigned product as safe – indicating that any efficacy difference was not achieved at the cost of tolerability.

These results are broadly consistent with the wider literature on topical anti-inflammatory therapy in AD, in which active topical agents have been shown to outperform comparator regimens on validated severity indices over similar treatment durations, while local tolerability profiles remain favorable.[4,11-18] As with other short-duration AD trials, a limitation of the present study is its 30-day follow-up period, which does not address durability of response or long-term safety; larger, multicenter, longer-duration studies would help confirm these findings and characterize the durability of benefit.

Conclusion

Nixoderm Tin demonstrated consistent and statistically significant improvement in AD/eczema severity over a 30-day period, evidenced by reductions in both EASI and ADSI scores and by increasingly favorable patient-reported outcomes, with no adverse events reported. The control group showed no comparable improvement and, on several measures, a slight increasing trend over the same period. These findings support the efficacy and tolerability of Nixoderm Tin as a topical therapy for mild-to-moderate AD, warranting further evaluation in larger, longer-duration, multicenter trials.

Ethical Approval

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and was approved by the Institutional Ethics Committee of The Oxford Medical College Hospital and Research Center, Bengaluru.

Author Contributions

Dr. Abhineetha Hosthota: Conceptualization, study design, patient recruitment, clinical assessment, data interpretation, manuscript preparation, critical revision, and final approval of the manuscript. Co-authors: Data collection, patient follow-up, data analysis, manuscript review, and final approval of the manuscript.

Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Acknowledgment

The authors acknowledge Ross Life science USA Inc for providing support for this study.

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