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Original Research Article

Open-label and single-arm clinical study to evaluate the efficacy and safety of EqualsTwo® skin healing cream in mild-to-moderate eczema

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ABSTRACT

Background: Atopic dermatitis (AD) is a chronic relapsing inflammatory dermatosis with substantial clinical and psychosocial burden. Safety concerns and poor adherence with corticosteroids and calcineurin inhibitors have increased interest in non-steroidal, plant based topical alternatives. This study aimed to evaluate the efficacy, tolerability, and patient-reported acceptability of EqualsTwo® Skin Healing Cream (Investigation product), a coconut-based emollient with botanical extracts in infants, children, and adults with mild-to-moderate eczema.
Methods: A 14-day open-label, single-arm, single-center study enrolled 58 participants (39 infants/children; 19 adults). Primary endpoints were the three-item severity (TIS) score (pediatric) and eczema area and severity index (EASI) score (adults). Secondary endpoints included Mexameter® MX 18 erythema assessment, skin pH measurement, dermatologist/pediatrician skin evaluations, and structured patient/parent-reported questionnaires. Nonparametric and paired statistical analyses were performed (significance: $p<0.05$).
Results: At day 14, adult EASI and pediatric TIS scores improved by 30.9% and 79.7%, respectively (both $p<0.0001$). Secondary outcomes showed a 7.6% erythema index reduction, modest pH normalization, and consistent improvements in dryness, pruritus, and irritation, with universal patient/parent satisfaction and no hypersensitivity reactions. Limitations include the uncontrolled open-label design, short duration, small sample (n=58), single-center recruitment, mild-to-moderate disease scope, and absence of validated quality-of-life or objective barrier function measures.
Conclusions: EqualsTwo® skin healing cream demonstrated statistically significant improvements in disease severity and symptom burden across pediatric and adult AD populations, with excellent tolerability and no adverse reactions. These findings support its potential as a safe, non-steroidal adjunct emollient therapy.

Keywords: Atopic dermatitis, Eczema, Plant preparations, Skin barrier, Dermatitis, Infantile

INTRODUCTION

Atopic dermatitis (AD), or eczema, is a chronic, relapsing inflammatory skin disease that frequently begins in infancy and persists variably into later life.[1-3] Globally, AD affects an estimated 15-20% of children and 2-10% of adults, with considerable variability across regions.[4] In India, population-based and hospital-based studies have reported prevalence ranging from 2% to 7% in children and up to 9% in mixed-age populations, indicating a substantial public health burden.[5] Beyond prevalence, AD significantly impairs quality of life, leading to sleep disturbances, impaired school and work performance, and psychological distress including anxiety and depression. The chronic and visible nature of lesions often exacerbates

stigma, thereby amplifying the psychosocial impact on patients and families.[6-8]

The pathophysiology of AD involves a complex interplay between epidermal barrier dysfunction, immune dysregulation, and environmental triggers.[9] Genetic predisposition, reduced filaggrin expression, dysbiosis of the skin microbiome, and heightened Th2-mediated inflammation contribute to disease onset and persistence.[10] Clinically, AD is characterized by intense pruritus, xerosis, erythema, and eczematous lesions, with infants and children typically exhibiting acute lesions with edema and excoriations. Left untreated, repeated scratching can lead to secondary bacterial infection and chronic lichenification. The recurrent nature of flares necessitates long-term treatment strategies that are safe, effective, and acceptable across age groups, particularly for infants and young children with delicate skin.[11,12]

Management of AD typically follows a stepwise approach, with daily emollient use forming the cornerstone of therapy.[13,14] Emollients improve hydration, restore the stratum corneum lipid matrix, and reduce flare frequency, while topical corticosteroids and calcineurin inhibitors are used for active inflammation. However, pharmacologic therapies carry notable limitations.[15] Prolonged or inappropriate corticosteroid use may cause cutaneous atrophy, striae, tachyphylaxis, and systemic absorption, contributing to steroid phobia and poor adherence.[16,17] Calcineurin inhibitors, though effective as steroid-sparing agents, are restricted by cost, tolerability issues such as burning and stinging, and long-term safety concerns. [18]

Natural and plant-derived ingredients have gained attention for their potential role in eczema management. Colloidal oatmeal has been shown to reduce inflammation and pruritus while supporting barrier repair.[19] Chamomile and witch hazel extracts demonstrate soothing, antioxidant, and anti-irritant properties, whereas *Centella asiatica* and *Glycyrrhiza glabra* facilitate wound healing and downregulation of inflammatory pathways.[20,21] Polyphenols from green tea and rosemary contribute antioxidant and antimicrobial effects.[22,23] Nutrient oils such as almond, flaxseed, borage, and olive are rich in essential fatty acids, which restore epidermal lipids and improve hydration.[24] Together, these components offer a multifaceted mechanism of action addressing dryness, erythema, pruritus, and barrier dysfunction the hallmark features of AD.

Restoration of epidermal barrier integrity through lipid replenishment, modulation of inflammatory mediators, and reduction of transepidermal water loss represents a pharmacologically rational approach in mild-to-moderate AD.[1,9]

EqualsTwo® skin healing cream (investigational product) is a coconut-based emollient containing botanical extracts and nutrient oils intended to support barrier restoration and modulate inflammation. Its composition included *Cocos nucifera* fruit oil; a botanical blend of *Chamomilla recutita* flower extract, *Centella asiatica* extract, *Glycyrrhiza glabra* root extract, *Camellia sinensis* leaf extract, *Polygonum cuspidatum* root extract, and *Rosmarinus officinalis* leaf extract; a phytoactive combination of coconut water, *Boswellia serrata* gum extract, and *Hamamelis virginiana* extract; and a nutrient oil blend of *Prunus amygdalus dulcis* oil, *Borago officinalis* seed oil, *Linum usitatissimum* seed oil, and *Olea europaea* fruit oil. Supportive ingredients included colloidal oatmeal, natural tocopherol, α-glucan oligosaccharide, *Salix alba* bark extract, and a natural preservative system. The formulation is designed to be hypoallergenic and devoid of potentially harmful chemicals, with the objective of providing adequate hydration, alleviating cutaneous inflammation, and restoring epidermal barrier integrity, while maintaining suitability for use in infants.

Given the clinical and psychosocial burden of AD in India and worldwide, coupled with the limitations of current pharmacological therapies, there is a compelling rationale to investigate safe, natural alternatives. Therefore, this study was conducted to assess the effectiveness of investigational product in reducing disease severity and associated symptoms in infants, children, and adults with mild-to-moderate eczema.

METHODS

Study design

This was an exploratory, interventional, non-randomized, single-arm, single-center study conducted at Cliantha Research, Ahmedabad, Gujarat, India, between February 2021 and July 2021.

Study population

Male and female participants aged from birth to 60 years (inclusive) were eligible. Neonates aged 0-7 days were required to have an activity, pulse, grimace, appearance, and respiration **(**APGAR) score >7 at both 1 and 5 minutes with no resuscitation at birth. Pediatric participants aged 0 months to 17 years with mild to moderate eczema determined by three-item severity (TIS) score at screening, and adults aged 18-60 years with mild to moderate eczema determined by the eczema area and severity index (EASI) score, characterized by moderate erythema (score 2) and mild scratch marks (score 1), were enrolled.

Participants were excluded if they were pregnant, lactating, or planning pregnancy during the study duration. Participants (or their parent/legal guardian/caregiver) unwilling to discontinue other body lotions/creams or any other face/body moisturizing products during the study were not enrolled. Participants with known allergy or sensitivity to cosmetic products and/or any ingredient of the investigational product were excluded. Participants currently enrolled in, or who had participated in, a similar clinical study within the prior 90 days were excluded.

Written informed consent was obtained from all adult participants and from parents/legal guardians of minors, with age-appropriate assent (verbal for 7-12 years; written for 12-18 years) and government-authorized proof of the child's eligibility.

Study endpoints

Primary endpoints were to assess the effect of the investigational product on affected skin using TIS in infants/children and EASI in adult participants at baseline (Day 1 pre-application) and post-application at 12 hours, 24 hours, day 7, and day 14. Investigator-assessed signs/symptoms and tolerability including mildness, gentleness, non-irritability, erythema/redness, dryness, itching, rashes, oedema, pruritus, and urticaria were recorded at the same time points. Participant/parent-reported outcomes were captured using a subjective self-assessment questionnaire at 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, 24 hours, day 7, and day 14.

Secondary endpoints included instrumental erythema was assessed on affected skin in infants/children and adults using the Mexameter® MX 18 at baseline (Day 1 pre-application) and post-application at 12 hours, 24 hours, day 7, and day 14. and the change in skin pH from baseline to day 14, determined by a calibrated skin pH meter.

Procedure

Participants were instructed to apply a thin layer of the investigational product (approximately 1.5-2.5 g) twice daily, in the morning and evening, to the affected areas for a duration of 14 days. Compliance was monitored using subject diaries that documented each application.

The study comprised five visits. At visit 1, participants were screened for eligibility. Eligible participants were enrolled at visit 2 (Day 1, baseline), where initial clinical and instrumental assessments were performed, and the test product was dispensed. Follow-up assessments were conducted at visit 3 (Day 2, 24±2 hours), visit 4 (Day 7±2 days), and visit 5 (Day 14±2 days). At each visit, dermatologists or trained pediatricians evaluated clinical outcomes using TIS and EASI scores, assessed changes in eczema-related symptoms, and monitored safety. Instrumental assessments, including erythema measurement by Mexameter® and skin pH analysis, were performed at predefined intervals. Subjective evaluations from adult participants and parental proxies for pediatric participants were collected at multiple time points, including 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, 24 hours, day 7, and day 14 after application.

Statistical analysis

All continuous variables were summarized as mean±standard deviation (SD). Changes in eczema severity and symptom scores (TIS and EASI) were analyzed using the Wilcoxon signed-rank test, while changes in instrumental measures (Mexameter® and pH) were evaluated using paired t tests. A two-sided p value of less than 0.05 was considered statistically significant. All analyses were performed using SPSS statistical software (version 25.0).

Ethical considerations

The study was conducted in accordance with the principles of the declaration of Helsinki and Good Clinical Practice (GCP) guidelines. Protocol was approved by the ACEAS, Independent Ethics committee. Written informed consent was obtained from all participants prior to enrolment. This clinical study was registered at CTRI (Clinical Trial Registry of India) under the trial registration number CTRI/2021/02/031511.

RESULTS

Baseline demographics

A total of 68 participants were screened of which 58 were enrolled and all completed the study. The study included three age-based groups comprising 19, 20, and 19 participants, respectively. Group 1 (0-36 months) had a mean±SD age of 13.6±7.7 months, group 2 (4-17 years) 6.8±3.3 years, and group 3 (18-60 years) 41.1±10.6 years. Male participants predominated in all groups (57.9%, 60.0%, and 73.7%, respectively), and all participants were of Asian ethnicity (Table 1).

Primary outcomes

EASI in adults

At baseline, the mean EASI score was 3.73±2.05, corresponding to mild eczema. No significant change was observed at 24 h post-application (3.72±2.06; p=1.0000). However, by day 7, scores had declined significantly by 13.7% to 3.13±1.43 (p<0.0001), and by day 14, a 30.9% reduction was achieved (2.43±0.95; p<0.0001) (Table 2).

TIS in infants and children

In the pediatric population, baseline TIS scores averaged 3.97±0.63, denoting moderate disease activity. A statistically significant reduction was evident as early as 24 h, with scores decreasing to 3.46±0.64 (12.2% reduction; p<0.0001). Marked improvements continued through the treatment period, reaching 1.90±0.79 at day 7 (52.3% reduction; p<0.0001) and 0.79±0.41 at day 14 (79.7% reduction; p<0.0001) (Table 2) (Figure 1 and 2).

Dermatological evaluation

Dermatologist and pediatrician evaluations demonstrated significant improvements in skin-related parameters over the 14-day treatment period (Table 3). Scores for mildness and gentleness on the skin improved steadily from baseline values of 1.86±0.35 to 2.28±0.59 at day 7 and 2.69±0.47

at day 14 for mildness, and to 2.28±0.59 and 2.62±0.56, respectively, for gentleness (all p<0.0001). Irritation decreased markedly from 4.10±0.72 at baseline to 3.76±0.80 at 24 h, 2.52±0.86 at day 7, and 1.05±1.03 at day 14 (p<0.0001). Similarly, redness/erythema and dryness showed progressive improvement by day 7, with further significant reductions by day 14 (both p<0.0001).

Symptom relief was also observed for itching, rash, edema, and pruritus. Itching scores reduced from 1.45±0.54 at baseline to 0.97±0.26 at day 7 and 0.33±0.47 at day 14 (p<0.0001). Rash scores fell from 1.03±0.37 to 0.48±0.54 at day 7 and nearly resolved by day 14 (0.05±0.22; p<0.0001). Edema reduced substantially by day 7 and was absent at day 14. Pruritus also improved significantly across timepoints (p<0.0001). Urticaria was minimally observed at the baseline (0.05±0.2) and it was completely resolved by day 14 (0.00). Pruritus was absent in 89.66% of subjects, while only 10.34% continued to experience it at a mild level (Table 3).

Subjective and parental assessments

By the end of the day 7 and 14 treatment period, 100% of respondents agreed or strongly agreed that the cream was smooth, gentle, and easily spreadable, provided a cooling sensation, and effectively softened, nourished, and hydrated the skin. All participants also reported that the product offered protection against dryness, aided relief from rashes and wound healing, and was non-greasy with quick absorption (Table 4).

Secondary outcomes

Change in erythema

Erythema demonstrated a consistent and statistically significant decline from baseline across all time points. Mean values decreased from 379.41±6.03 at baseline to 372.90±6.13 at 12 h and 366.84±6.47 at 24 h, with further reductions observed on day 7 (358.51±7.10) and day 14 (350.44±6.99) (all p<0.0001). This corresponded to a cumulative reduction of 7.6% by study end.

Change in skin pH

Skin pH showed a modest but statistically significant increase, shifting from 4.65±0.08 at baseline to 4.75±0.08 at day 14 (p<0.0001) (Table 5).

Safety outcomes

The 100% subjects have no skin hypersensitivities like erythema/redness, oedema, pruritus, urticaria while using the investigation product. By the end of the study, no participants showed signs of erythema, dryness, edema, urticaria, allergic reactions, or any other dermatological symptoms.

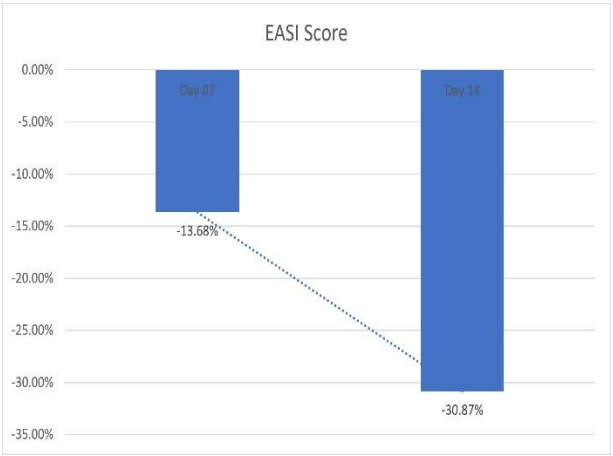

Figure 1: Change in EASI score over time following application of EqualsTwo® skin healing cream.

Figure 2: Change in TIS score over time following application of EqualsTwo® skin healing cream.

Table 1: Summary of demographic characteristics of study participants.

Variables	Group 1 (0-36 months), (n=19)	Group 2 (4-17 years), (n=20)	Group 3 (18-60 years), (n=19)
Gender	Female-8 (42.1) Male-11 (57.9)	Female-8 (40.0) Male-12 (60.0)	Female-5 (26.3) Male-14 (73.7)
Race	Asian-19	Asian-20	Asian-19
Age	13.6±7.7 months	6.8±3.3 years	41.1±10.6 years

Table 2: Change in EASI and TIS scores over time.

Parameters	Baseline (Day 1)	24 h (Day 2)	Day 7	Day 14	% change from baseline at day 14	P value
EASI score (Adults)	3.73±2.053	3.72±2.056	3.13±1.426	2.43±0.948	-30.87%	<0.0001
TIS score, (Infants/children)	3.97±0.628	3.46±0.643	1.90±0.788	0.79±0.409	-79.74%	<0.0001

Table 3: Pediatrician/dermatologist assessment parameters.

Parameters	Baseline	24 h	Day 7	Day 14	Change from baseline at day 14	P value
Mildness on skin	1.86±0.348	1.88±0.329	2.28±0.586	2.69±0.467	0.83	<0.0001
Gentleness on skin	1.86±0.348	1.88±0.329	2.28±0.586	2.62±0.557	0.76	<0.0001
Irritation	4.10±0.718	3.76±0.802	2.52±0.863	1.05±1.033	-3.05	<0.0001
Redness/ erythema	1.22±0.460	1.17±0.381	1.03±0.184	0.40±0.493	-0.83	<0.0001
Dryness	1.34±0.548	1.33±0.509	0.93±0.454	0.22±0.421	-1.12	<0.0001
Itching	1.45±0.535	1.31±0.503	0.97±0.263	0.33±0.473	-1.12	<0.0001
Rash	1.03±0.373	0.97±0.323	0.48±0.538	0.05±0.223	-0.98	<0.0001
Edema	0.29±0.496	0.21±0.450	0.02±0.131	0.00±0.000	-0.29	<0.0001
Pruritus	0.45±0.753	0.45±0.753	0.33±0.543	0.12±0.329	-0.33	<0.0001

Table 4: Subjective self/parental assessment at day 7 and day 14.

Parameters	Agreement (%)
Smooth and gentle on skin	100
Easily spreadable	
Cooling sensation	
Softens and nourishes skin	
Soothes and hydrates	
Protects against dryness	
Relief from rashes and quick wound healing	
Non-greasy, quick absorption	
Fragrance likeability	
Overall satisfaction	

Table 5: Change in Mexameter erythema and skin pH over time.

Parameters	Baseline	Day 2 (24±2 hrs)	Day 7 (±2 days)	Day 14 (End of study)	P value*
Mexameter erythema (AU)	379.41±6.03	366.84±6.47	358.51±7.10	350.44±6.99	<0.0001 (all timepoints)
Skin pH	4.65±0.080	-	-	4.75±0.075	<0.0001 (Day 14 vs Baseline)

*mark represents significant changes in respective parameters where p value is less than 0.05.

DISCUSSION

This open-label, single-arm study revealed consistent and statistically significant improvement across physician severity scores, investigator skin parameter assessments, instrumentally measured erythema, and patient/parent-reported outcomes. The investigation product was well tolerated, with no serious adverse events or hypersensitivity observed. Taken together, these findings support the utility of barrier-enhancing, non-steroidal formulations in managing AD in mixed-age populations.

In our adult cohort, the EASI score improved from 3.73±2.05 at baseline to 2.43±0.95 at day 14, representing a 30.9% reduction (p<0.0001). In infants and children, the TIS score declined from 3.97±0.63 to 0.79±0.41 (-79.7%) (p<0.0001). These magnitudes are broadly comparable to published emollient or barrier-based interventions. For example, in a 14-day single-arm trial of 1% colloidal oatmeal cream, Lisante et al reported that by day 14, 82.8% of participants achieved ≥20% EASI improvement, indicating a robust response in a mild-to-moderate AD population.[25] In another controlled study, an eczema cream

containing 1% colloidal oat reduced mean EASI by approximately 51% at day 14 (compared with a standard moisturizer), reflecting a stronger relative effect than ours but in a different population and formulation.[26] The observed improvement may be attributable to barrier lipid replenishment, anti-inflammatory phytoconstituents, and emollient-mediated reduction in transepidermal water loss. However, mechanistic biomarkers were not evaluated. The pronounced improvement in TIS score is clinically meaningful, as TIS is highly sensitive to early inflammatory changes in pediatric eczema, and such reductions indicate effective short-term barrier restoration and symptom control in younger patients.

Investigator-assessed skin parameters such as irritation, redness, dryness, and itching showed marked reductions over 14 days with erythema reducing by 7.6%. In the literatures, Hon et al showed significant erythema index reduction following emollient use in pediatric eczema, though precise percentages were not stated. Similarly, in the JDD study of 1% colloidal oat eczema cream, erythema and skin barrier metrics improved in parallel to a 51% EASI reduction.[27] Our modest pH increase (4.65→4.75) is also directionally aligned with barrier restoration theory; the JDD oat-cream study reported significant improvement in skin pH and hydration over 14 days.[25] The fact that our subjective assessments showed 100% agreement on smoothness, ease of spread, and overall satisfaction further reinforces the acceptability of this formulation. In comparison, Rennó et al evaluated a colloidal oat cream and reported an 83% completion rate with clear or almost clear skin by day 21, along with improvement in patient-oriented eczema measure (POEM) scores of 74%.[28]

Clinical implications are that such a formulation may serve as a steroid-sparing adjunct or baseline therapy in mild-to-moderate eczema across age groups. Early barrier support may reduce flare frequency, reduce reliance on corticosteroids, and improve patient adherence and satisfaction.

Limitations

In our observation the present study is however limited by its single-arm design, short 14-day duration, and modest sample size, which restrict the ability to attribute effects definitively or assess long-term outcomes.

CONCLUSION

This open-label, single-arm study demonstrated that EqualsTwo® skin healing cream (Investigation product) provided significant clinical and symptomatic improvement in infants, children, and adults with mild-to-moderate eczema, while being safe and well tolerated. The findings highlight the potential of natural, barrier-enhancing formulations as steroid-sparing alternatives in routine management. Nonetheless, the short treatment duration and absence of a comparator arm limit definitive conclusion. Overall product is effective and safe to use for paediatric and adult population.

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