A Multicenter, Prospective, Non-Comparator, Open-Label Study of the Safety and Efficacy of NEOCERA™ Cream with Ceramides in Subjects with Atopic Dermatitis

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Abstract

Atopic dermatitis (AD) is a chronic, itchy skin condition that is very common in children but may occur at any age. Ceramides are known to play an essential role in structuring and maintaining the water permeability barrier function in skin. This study was designed to evaluate the safety and efficacy of NEOCERA™ Cream with Ceramides in patients with atopic dermatitis. This 4-week, open-label study enrolled 15 patients with mild to moderate atopic dermatitis. Study medication was applied to the affected area twice daily. Fourteen patients completed the study; one subject discontinued treatment at Week 1 with no reason provided. All adverse events (AEs) were recorded. Disease severity was measured at Baseline, Week 1, Week 2 and Week 4 (End of Treatment) by Investigator Global Assessment (IGA), Body Surface Area (BSA) and Investigator Evaluation of Signs and Symptoms. Compliance was determined from subject diaries at Week 12. Subject satisfaction was determined by a 16-point survey instrument completed at End of Study visit. There were no AEs reported with the application of study medication. All subjects who completed the study experienced a marked improvement in their atopic dermatitis. IGA improved by 86% and BSA improved by 57% in subjects who completed the study. Investigator Evaluation of Signs and Symptoms demonstrated improvements in erythema (79%); induration/papulation (86%); excoriations (93%); lichenification (71%); oozing/crusting (21%); and scaling (50%). Compliance with the regimen was excellent and study subjects expressed an overwhelming satisfaction with the medication with no report of irritation. The study demonstrated that NEOCERA™ Cream with Ceramides is an effective non-irritating, non-steroidal treatment in subjects with atopic dermatitis.

Introduction

Atopic dermatitis (AD) is a chronic, itchy skin condition that is very common in children but may occur at any age. It is also known as eczema and atopic eczema. It is the most common form of dermatitis. AD is more likely to occur in atopic patients with history of asthma and hay fever (allergic rhinitis). Often these conditions run within families, with a parent, child, or sibling also affected. Therefore, a family history of asthma, eczema, or hay fever is particularly useful in diagnosing AD in infants.

There is no known cure for AD. The most common treatments include topical steroids, systemic corticosteroids, topical immunomodulators, antihistamines, and phototherapy. A mid- or high-potency steroid cream is often prescribed for treatment. Oral steroids are often administered when there is an extensive amount of skin involved. Although topical steroids have tremendous benefit in reducing inflammation, they are also responsible for significant side effects, especially noted with long-term use.

Methods

- Multicenter, open-label study enrolled 15 subjects ages 2 and above with a clinical diagnosis of atopic dermatitis. Mean age was 41 years (9 females, 6 males, 12 white, 3 black).
- Fourteen subjects successfully completed the study; one subject discontinued at Week 1 with no reason provided.
- Each subject who completed the study participated for 4 weeks. Subjects were seen at baseline, Week 1, Week 2 and Week 4 (End of Treatment) for clinical evaluations, compliance, and satisfaction determinations.
- Study medication (NEOCERA™ Cream with Ceramides) was applied twice a day.
- Efficacy was assessed utilizing the following methods: IGA of AD (Table 1); Investigator and Evaluation of Signs and Symptoms of AD (Table 2); and BSA. A two-tailed t-test was used to measure the significance of the differences in scores from baseline to Week 4.
- At the end of the study, subjects were asked to complete a treatment evaluation survey assessing their satisfaction with the product (Table 3).

Table 1. Investigator Global Assessment

Score	Category	Definition
0	Clear	No inflammatory signs of AD
1	Almost Clear	Faint, barely detectable erythema and/or trace residual induration/papulation in limited areas; neither excoriation nor oozing/crusting are present
2	Mild	Light pink erythema and slightly perceptible induration/papulation; excoriation, if present, is mild
3	Moderate	Dull red, clearly distinguishable erythema and clearly perceptible induration/papulation, but not extensive; excoriation or oozing/crusting, if present, are mild to moderate.
4	Severe	Deep/dark red erythema, and marked and extensive induration/papulation; excoriation and oozing/crusting are present.

Table 2. Investigator & Subject Evaluation of Atopic Dermatitis

Erythema (E)	Induration/Papulation (I/P)	Excoriations (Ex)
0 None	0 None	0 None
1 Faintly detectable erythema; very light pink	1 Barely perceptible induration/population	1 Scant evidence of excoriations with no signs of deeper skin damage (erosion, crust)
2 Dull red, clearly distinguishable	2 Clearly perceptible induration/population but not extensive	2 Several linear marks of skin with some showing evidence of deeper skin injury (erosion, crust)
3 Deep/dark red	3 Marked and extensive induration/papulation	3 Many erosive or crusty affected area
Lichenification (L)	**Oozing/Crusting (O)**	**Scaling (S)**
0 None	0 None	0 None
1 Slight thickening of the skin discernible only by touch and with skin markings minimally exaggerated	1 Evidence of exudation	1 Evidence of small, dry, thin, exfoliation from the upper layers
2 Definite thickening of the skin with skin markings exaggerated to that they form a visible criss-cross pattern	2 Serous brown, yellow or green exudations and/or drying of the discharge	2 Definite exfoliation from the upper layers
3 Thickened indurated skin with skin markings visibly portraying an exaggerated criss-cross pattern	3 Many dry scabs and/or exudations	3 Marked and extensive exfoliation from the skin

Table 3. Subject Compliance and Satisfaction Evaluation

1. Strongly disagree; 2. Disagree; 3. Neither agree nor disagree; 4. Agree; 5. Strongly agree	
Study Medication made my condition better.	4.64
Study Medication works better than other products I have used.	4.43
I did not experience any irritation or burning with Study Medication.	4.43
Study medication rapidly absorbs into the skin.	4.50
Study Medication is easy to use.	5.00
I like how Study Medication feels on the skin.	4.86
Study Medication meets my expectations in terms of results.	4.64
I used Study Medication more regularly than other products I have used.	5.00
Overall, I am satisfied with the performance of Study Medication.	4.79

Results

- Fourteen subjects successfully completed the study from Baseline through Week 4.
- No AEs were reported with the use of the study medication.
- Efficacy evaluation was measured by the median point decrease in the IGA, BSA, and Investigator Evaluation of Signs and Symptoms from baseline to Week 4.
- Baseline IGA was defined as mild to moderate (median 3.00). At the End of Study Week 4, IGA median score was 1.00. This represented a median improvement of 2.00 from Baseline to Week 4, which was found to be statistically significant ($p<0.005$).
- Baseline BSA was defined as mild to moderate (median 3.00). At the End of Study Week 4, BSA median score was 2.00. This represented a median improvement of 1.00 from Baseline to Week 4, which was found to be statistically significant ($p<0.05$).
- Investigator evaluation of signs and symptoms from Baseline to End of Study (Week 4) were as follows:
  - Erythema mean score was 1.87 at Baseline and 0.93 at End of Study.
  - Induration/Papulation mean score was 1.60 at Baseline and 0.64 at End of Study.
  - Excoriations mean score was1.53 at Baseline and 0.21 at End of Study.
  - Lichenification mean score was 1.40 at Baseline and 0.50 at End of Study.
  - Oozing/Crusting mean score at Baseline was 0.33 and 0.07 at End of Study.
  - Scaling mean score at Baseline was 1.27 and 0.57 at End of Study.
- Throughout the study, compliance was calculated from the number of applications documented in the subject diary and presented as a percentage of total recommended applications for the course of the study. Compliance with the study medication was high. Ten subjects achieved 100% compliance; 4 subjects achieved compliance of 92% to 99%.
- All subjects who successfully completed the study also completed the end-of-treatment survey. Overall subjects were extremely satisfied with the product (Table 3).
- Figures 1 and 2 show improvement from Baseline to End of Study in 2 study participants.

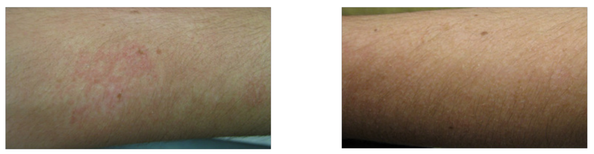

Figure 1: Atopic dermatitis on the arm of a study participant at Baseline (left) and End of Study (right) after treatment with NEOCERA™ Cream with Ceramides

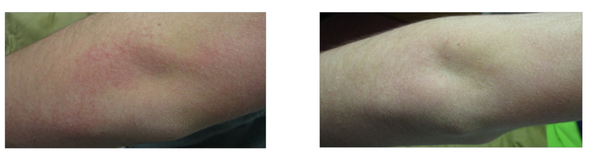

Figure 2: Atopic dermatitis on the elbow of a study participant at Baseline (left) and End of Study (right) after treatment with NEOCERA™ Cream with Ceramides

Conclusion

NEOCERA™ Cream with Ceramides is an effective treatment in subjects with atopic dermatitis. It allows enhanced efficacy, no irritation, ease-of-use and, most importantly, provides a highly effective non-steroidal alternative treatment for atopic dermatitis.