

Evaluating the Tolerance and Safety of a Colloidal Oatmeal Cream and Cleanser in Babies and Children with Atopic Dermatitis

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ABSTRACT

Atopic dermatitis, the most common type of the eczema, affects approximately 17% of children. Of these children, 60% exhibit symptoms of atopy prior to the age of one while 85% develop symptoms by the age of five. Over 60% of infants with atopic dermatitis continue to have one or more symptoms of atopy into adulthood.

Atopy is an inflammatory skin disease characterized by intense pruritis and inflamed skin. In atopic infants, red, weeping lesions may appear on cheeks, scalp, wrists and exterior legs with an overall xerosis. An infant will constantly rub their body or face against objects such as bedding to alleviate the itch. In children, atopy can appear in different areas such as the flexural extremities, the neck, creases of thighs, and ankles. In all atopic patients, moisturization and gentle skin cleansing is one of the best first line defenses. A gentle skin care moisturization regimen is especially important in atopic babies under the age 2 who have limited topical prescription medications available to them and those available need be utilized under careful medical supervision. Moisturization, accompanied with gentle cleansing, using a skin care regimen containing occlusives, skin protectants, and free of potentially irritating ingredients will help protect the stratum corneum while keeping the skin properly hydrated.

A 4-week clinical tolerance study was performed utilizing a colloidal oatmeal cream and cleanser on babies and children (2 months to 6 years old) with mild to moderate atopic dermatitis as determined by the criteria of Hanifin and Rajka. Twenty-five patients were enrolled into the study. All patients applied the occlusive colloidal oatmeal cream, with ceramides and panthenol, twice a day to the entire body. The colloidal oatmeal-based glycerin cleanser was used for all routine bathing. An independent pediatric dermatologist performed evaluations on skin condition at weeks 0, 2, and 4.

The colloidal oatmeal skin care regimen was well tolerated in babies and children with no significant increases in clinical safety parameters. Itch assessments showed significant improvements ($p < 0.05$) as determined by VAS scoring. In addition, there were no significant increases in eczema severity, as determined by the Investigators Global Assessment, while dermatologist assessments showed improvements in overall skin condition indicating significant skin benefits when using this colloidal oatmeal regimen in babies and children. Standardized Quality of Life Indices also indicated that the improvement in skin condition of these atopic patients also led to an improved Quality of Life.

STUDY DESIGN

This was a four-week, monadic study to assess the safety and tolerance of a colloidal oatmeal regimen (cream and cleanser) on babies and children with mild to moderate atopic dermatitis.

Population

Twenty-three male or female children between the ages of 2 months to 6 years completed the study, the mean population age was 2.4 years. To qualify, patients had to have mild to moderate atopic dermatitis according to the criteria of Hanifin and Rajka with at least 5% Body Surface Area (BSA) involved. Patients were excluded if they exhibited cutaneous bacterial or fungal infections. Topical eczema treatments already in use were continued. This protocol was approved by an IRB and informed consent was obtained from the patient's parent or legal guardian.

Treatments

All patients used the occlusive colloidal oatmeal cream twice a day and the colloidal oatmeal glycerin cleanser was used for all routine bathing. The test products were as follows:

Colloidal Oatmeal Cream (containing Avenanthramides, Ceramides and Panthenol)

Colloidal Oatmeal Cleanser

Evaluations

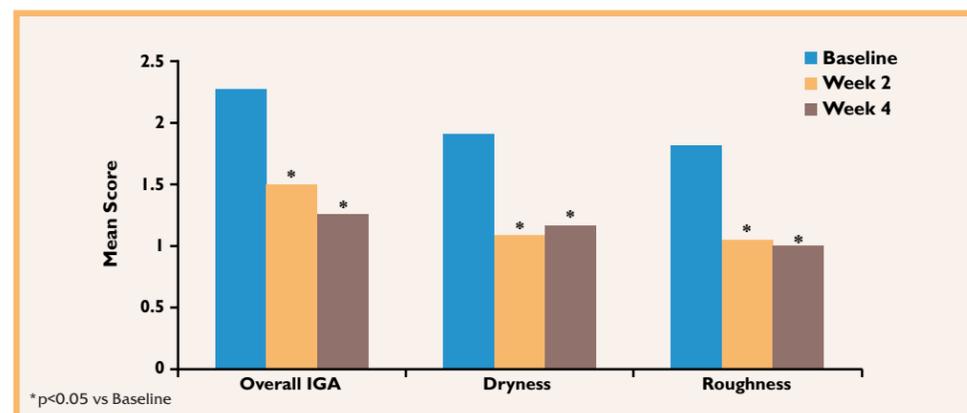
Clinical evaluations were performed at baseline, Weeks 1 and 4. These included:

- Dermatologist grading for Investigators Global Assessment (IGA) and other cutaneous and dryness parameters
- Standardized Infant/Child Dermatitis Quality of Life Index completed by child (age dependant) or parent/legal guardian (baseline and week 4)
- Itch assessment utilizing Visual Analog Scoring

RESULTS

This moisturizing skin care regimen consisting of a colloidal oatmeal cleanser and occlusive cream with ceramides, avenanthramides and panthenol was well tolerated by babies/children with mild to moderate atopic dermatitis. There were no significant increases in the mean scores for eczema severity, itch or other cutaneous irritation parameters. Twenty-five patients were enrolled and twenty-three completed the study. No serious skin reactions were reported.

Figure 1. Dermatologist Assessments: IGA and Dry Skin Parameters



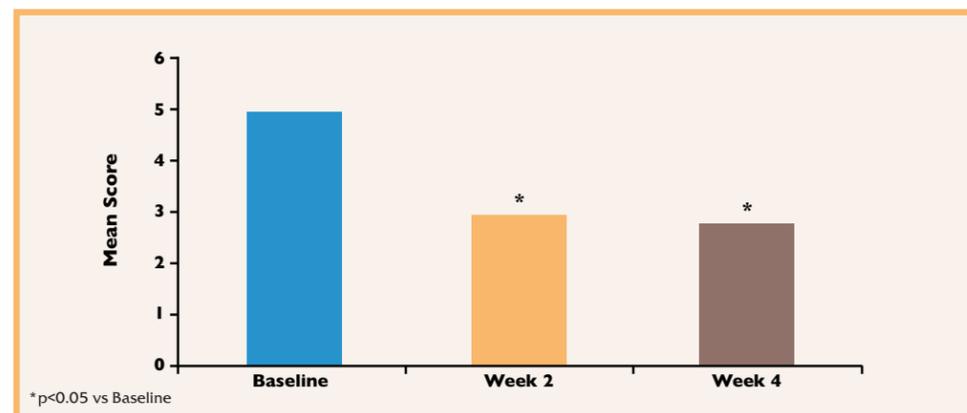
Dermatologist assessments showed significant improvements ($p < 0.05$) in the mean eczema severity score, skin dryness and roughness after 2 weeks of using the colloidal oatmeal skin care regimen. After 4 weeks of using the regimen there was a 48% improvement in the mean IGA.

Table 1. Investigator Global Assessment

	Percent of Subjects in Each IGA Category	
	Baseline	Week 4
Severe	-	-
Moderate	73%	4%
Mild	27%	36%
Almost Clear	-	43%
Clear	-	17%

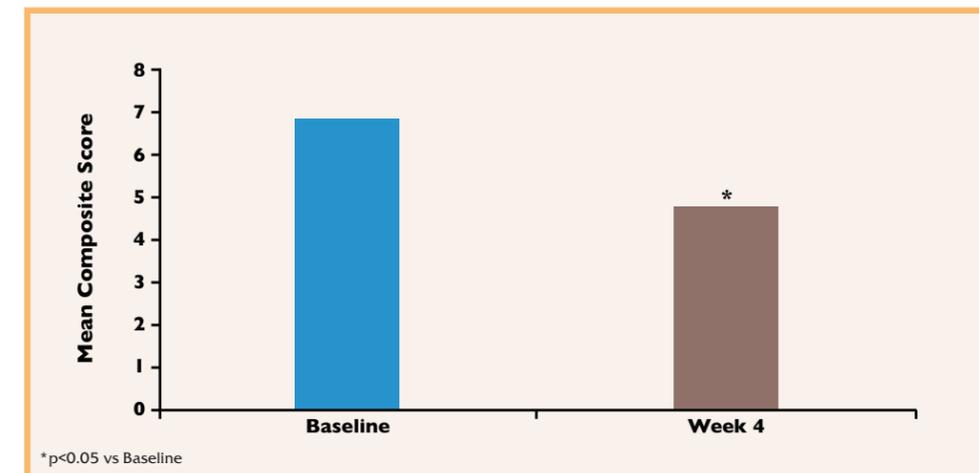
Improvements in the severity of eczema, as determined by specific IGA categories, were observed in patients that used the colloidal oatmeal regimen for 4-weeks. At the baseline visit, 73% of the population exhibited a moderate score for eczema severity, after using the regimen for 4 weeks only 4% exhibited a moderate eczema severity score.

Figure 2. Mean Itch Score (Visual Analog Scale)



Significant improvements in itching ($p < 0.05$), as determined by the Visual Analog Scale (VAS), were perceived after 2 weeks of using the colloidal oatmeal skin care regimen. Significant improvements in the mean itch score were maintained at the 4-week timepoint, with a 45% improvement in the mean itch score when compared to baseline.

Figure 3. Quality of Life: Babies/Children



It is well documented using standardized Quality of Life Indices (QOL) for various dermatosis that an improvement in skin condition can have a positive effect on the patients' overall quality of life. The higher the QOL score, the more impaired the patients quality of life, therefore a decrease in QOL scoring would indicate an improvement in the patients overall quality of life (i.e. mood, playtime, sleep).

Significant improvements in overall skin condition after 4-weeks use of the colloidal oatmeal cream and cleanser regimen resulted in an overall improvement in the babies/children overall quality of life

CONCLUSIONS

This moisturizing regimen consisting of a mild colloidal oatmeal cleanser and occlusive cream was well tolerated and beneficial to babies and children with mild to moderate atopic dermatitis.

- Dermatologist evaluations showed significant improvements ($p < 0.05$) in the Investigators Global Assessment (IGA) of Eczema Severity after 2 and 4 weeks of use. Improvements in IGA severity scoring were observed with a high percentage of patients exhibiting moderate eczema upon study enrollment and the majority of patients, after 4 weeks of regimen use, exhibiting mild/almost clear IGA scores.
- Dermatologist evaluations showed significant improvements ($p < 0.05$) in overall dryness and roughness after 2 and 4 weeks of use.
- Significant improvements ($p < 0.05$) in itching were perceived after 2 and 4 weeks using the regimen.
- Improvements in skin condition resulted in overall improvements in the Quality of Life after 4 weeks of using the regimen as determined by standardized Baby/Child Quality of Life Indices for Dermatitis.

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