INTRODUCTION

Topical corticosteroids are recommended for the treatment of atopic dermatitis (AD). Corticosteroid efficacy has been demonstrated with a wide variety of preparations and strengths but these agents have the potential for topical and systemic side effects, including striae, skin atrophy, perioral dermatitis, acne rosacea, and adrenal suppression. Patients’ fears about these side effects have important implications for compliance with corticosteroid treatment. An anhydrous, preservative-free, fragrance-free, over-the-counter (OTC) zinc oxide cream containing 15% zinc oxide, 2% colloidal oatmeal, 1% allantoin, and natural oil was developed for treatment of dermatitis lesions. The objective of this trial was to compare clinical efficacy and safety of this OTC zinc oxide cream.

STUDY DESIGN

Subjects

Volunteer subjects were recruited from a pool of healthy men and women, 18.4 years of age with Fitzpatrick skin type IV. Subjects had clinically determined mild-to-moderate eczema or AD with a SCORing Atopic Dermatitis (SCORAD) score ≥ 25, 65% of total body area affected, and at least one active lesion.

Design

This was a 6-week, single-center, double-blind, randomized, controlled clinical trial in Colorado Springs, Colorado. The study consisted of a visit at baseline and again after two and four weeks. At each visit, SCORAD Investigators’ Global Improvement Assessment (IGA), Dermatologist Life Quality Index (DLQI), and transepidermal water loss (TEWL) were used to evaluate efficacy. Safety and tolerability were evaluated by recording adverse events and assessing signs and symptoms, including erythema, dryness/scaling, peeling, exema, burning, pruritis, tightness, and tingling in the area adjacent to the target lesion.

Randomization

Subjects were randomized (1:1) to the test cream (EB: SkinKline (Creams) or EB 1% hydrocortisone cream (HC)). Subjects were provided with a preweighted unit of their assigned treatments and instructed to apply a sufficient amount of the test material to all affected areas and adjacent skin 2 times per day (dissolved morning and evening) to clean dry skin, especially after bathing. The EB ingredients include zinc oxide, colloidal oatmeal, allantoin, sweet almond oil, beeswax, vitamin E, propolis, paraffin, and sorbitol.

Assessments

Efficacy assessments included the SCORAD, IGA (score from 0-5 with 1= worse and 5= markedly improved), and the DLQI. Transepidermal Water Loss (TEWL) was measured using a Circular Array Analyzer (CAAS 2000, Courage HÜK) at baseline and at week 4. Subjective assessment of erythema, dryness/scaling, peeling, exema, burning, pruritis, and tingling were measured at baseline and at week 4.

RESULTS

Subjects

A total of 38 subjects were enrolled and 32 completed the trial and comprised the per protocol population (EB = 17, HC = 15). One subject randomized to EB withdrew and did not complete the study. The mean age was 45.8 ± 9.3 years and the majority of subjects were female (78.3%) and Caucasian (78.3%). Subjects in the two treatment groups were well matched for age, sex, race, ethnicity, and skin type.

Global Improvement

Both treatments resulted in significant improvements from baseline in IGA at weeks 2 and 4 (p < 0.001) and there was no significant difference between treatments at either time point (Figure 1).

CONCLUSION

The results from this single-center, double-blind, randomized, controlled clinical trial indicate that application of the OTC cream to affected areas and adjacent skin for 4 weeks in patients with eczema resulted in significant decreases from baseline in the signs and symptoms of this disease. This cream, containing 15% zinc oxide, 2% colloidal oatmeal, 1% allantoin, and natural oil is safe and effective as a hydrocortisone cream for the treatment of eczema. The equivalence of this nonsteroidal preparation versus a corticosteroid cream supports the efficacy of a steroid-sparing approach for the treatment of eczema. Therefore, this cream can be a valuable addition to the dermatologic armamentarium, offering an additional avenue for enhancing the safety of treatment for this disease.

Table 1. SCORAD scores

<table>
<thead>
<tr>
<th>Score</th>
<th>Mean change % from baseline at week 2</th>
<th>p-value</th>
<th>Mean change % from baseline at week 4</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGA</td>
<td>EB</td>
<td>-25.2</td>
<td>0.001</td>
<td>-38.8</td>
</tr>
<tr>
<td></td>
<td>HC</td>
<td>-0.4</td>
<td>0.004</td>
<td>-0.4</td>
</tr>
<tr>
<td>Erythema score</td>
<td><strong>P</strong></td>
<td>-58.2</td>
<td>0.001</td>
<td>-58.6</td>
</tr>
<tr>
<td>Subjective symptoms score</td>
<td></td>
<td>-54.0</td>
<td>0.001</td>
<td>-54.0</td>
</tr>
<tr>
<td>Overall SCORAD score</td>
<td></td>
<td>-46.9</td>
<td>0.001</td>
<td>-46.9</td>
</tr>
</tbody>
</table>

Skin barrier

Assessments of TEWL indicated that EB treatment resulted in significant reductions from baseline at both weeks 2 and 4 (p < 0.05 and p < 0.001, respectively). EB treatment also resulted in a significant reduction from week 2 to week 4 (p < 0.025). Treatment with HC resulted in a significant reduction in TEWL at week 2 only (p < 0.05). There were no significant differences between treatments for changes from baseline in TEWL at weeks 2 or 4 (Figure 2).

Figure 1. IGA

Figure 2. TEWL

Extract and severity of eczema

Both treatments were associated with significant improvements from baseline in area score “A,” intensity score “B,” subjective symptoms score “C,” and overall SCORAD score at weeks 2 and 4 (p < 0.05). There were no significant differences between treatments for changes from baseline in any of these composite measures at weeks 2 or 4 (Table 3).