

Pilot Trial of Isopropyl Myristate / Zinc Pyrithione Kit for Treating Severe Dandruff

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Background

The disease commonly known as “dandruff” is caused by numerous host factors in conjunction with the normal flora yeast *Malassezia furfur* (*Pityrosporum ovale*). Similarly these factors also play a major role in seborrheic dermatitis. Currently, most commercially available hair shampoos publicize that they contain some form of traditional antifungal agent(s) or “natural” tea tree oil, however published clinical trials show that there is considerable variation in therapeutic results amongst all the different brands. It is believed that the largest challenge of using only a “topical shampoo” to treat the disease is that shampoos are washed out of hair, and off the scalp, almost immediately after application, leaving only a thin residue of active ingredient behind. Alternatively, corticosteroids and antifungal creams have sometimes been used for overnight treatment, yet chronic use of corticosteroids may be associated with skin atrophy, increased intraocular pressure, and other problems. Consequently, a new product named *DermaZinc™ Spa Scalp Treatment Kit* (Dermalogix Partners, Scarborough, Maine) has been developed as a two-part (liquid drops and shampoo) regimen and is thought to be the first dual-modality OTC dandruff / seborrheic dermatitis treatment of its kind. Both drops and shampoo use zinc pyrithione as its active ingredient in combination with an isopropyl myristate vehicle that greatly enhances treatment speed by allowing rapid absorption into the scalp. The manufacturer recommends that the drops be applied overnight for one week and then used once weekly as a maintenance product. The manufacturer also recommends that the shampoo be used daily. The manufacturer claims that when drops and shampoo are used together, consumers can feel relief from their symptoms within 24 to 78 hours and that there will be clearing of the scalp condition within one (1) week. They have also found that the *DermaZinc™ Spa Scalp Treatment Kit* works consistently ten (10) times better than leading dandruff shampoos that contained tea tree oil as the active ingredient.

Objectives

This open-label, pilot trial assessed the efficacy and tolerability of *DermaZinc™ Spa Scalp Treatment Kit* in the treatment of dandruff and seborrheic dermatitis in 40 subjects. Participants ranging in age from 21 to 75 years old used the *DermaZinc™ Spa Drops* in the evening as directed by the manufacturer, and they used *DermaZinc™ Spa Shampoo* each morning on the involved areas for one week. Clinical measures of improvement included erythema, scaling, and pruritus. The manufacturer desired to generate data that would allow them to claim that the *DermaZinc™ Spa Scalp Treatment Kit*: 1) was safe to use as directed; 2) generated significant relief from symptoms even after only one use; and 3) virtually completely resolved seborrheic dermatitis in most subjects within just one (1) week of use.

Results

All participants completed the study. Clinical assessments were performed daily over the course of one (1) week of treatment (drops and shampoo were used daily). There was also a clinical inspection of the scalp three (3) weeks after initial therapy began to assess recurrence rate post-treatment (drops used only once weekly). Beneficial effects were evidenced in 80% of subjects after just one day of use. All subjects achieved a mean 73% improvement in the total dandruff severity score after treatment day 3. After the full one (1) week of therapy was completed, a mean 96% improvement in the total dandruff severity score was achieved. The recurrence rate after three (3) weeks was less than 5%. All subjects noted a marked decrease in the severity of their condition at the conclusion of the study. The formulations were well tolerated and there were no adverse events.

Limitations

This was an open-label pilot trial limited to just 40 participants, with no control or placebo group.

Conclusions

The topical use of *DermaZinc™ Spa Scalp Treatment Kit* may be considered to be an excellent alternative therapeutic modality for treating severe dandruff and seborrheic dermatitis. The product was proven safe to use every day. A large majority of subjects found relief of symptoms after just one use. This very rapid effect may likely be attributed to the unique combination zinc pyrithione / isopropyl myristate formula not found in other commercially available products. Seventy-three percent (73%) clinical improvement was noted after just three (3) days and ninety-six percent (96%) improvement was achieved by the end of the one week study. Additionally, once weekly use of the drops was proven to work well as a maintenance regimen. It is concluded that *DermaZinc™ Spa Scalp Treatment Kit* is likely clinically superior to other commercially available “shampoo only” solutions. All manufacturers marketing claims described in the “Objectives” section of this report have been verified to be true.