

# A comparative randomized clinical study assessing the effect of a 1% selenium disulfide-based shampoo versus 2% ketoconazole shampoo in subjects presenting with moderate to severe scalp seborrheic dermatitis

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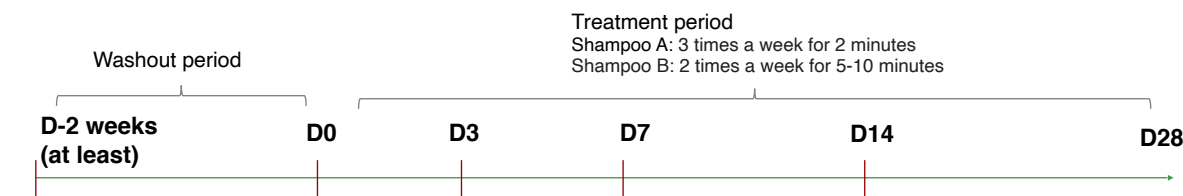
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## 1 INTRODUCTION AND OBJECTIVES

Scalp seborrheic dermatitis (SSD) greatly impacts the quality of life. In this study, we aim to evaluate both the efficacy and the effect on quality of life of a shampoo (Shampoo A) containing 1% Selenium disulfide and 1% salicylic acid in patients with moderate to severe scalp seborrheic dermatitis, compared to a reference shampoo containing 2% ketoconazole (Shampoo B).

## 2 METHODOLOGY

This multi-centric double-blinded randomized study was conducted on 2 parallel groups of subjects presenting with moderate to severe seborrheic dermatitis. This was assessed through the Symptom Scale of Seborrheic Dermatitis assessment (SSSD) [score >6] based on photographic atlas.



- Scalp examination:
- SSSD, from 0=none to 15=very severe, comprising 2 subscores ranging each from 0=none to 5=very severe for erythema and scales, and a visual analogue scale ranging from 0 mm=none to 100 mm= very severe itching)
  - Total scales score (sum of adherent and non-adherent) ranging from 0= none to 10= very large quantity of scales
  - Erythema and greasiness; 0= none to 5 = severe
  - Self-evaluations (Quality-of-Life questionnaire (QoL Scalpdex)), discomfort evaluations and self-assessment of hair quality.

The related study endpoints of interest were the reduction in SSSD, scales (adherent and non-adherent), itching and erythema. The efficacy of Shampoo A was compared to Shampoo B using an analysis of covariance on the change from baseline as response variable.

## 3 RESULTS

The panel consisted of 64 male and female subjects of European, Hispanic, Asian, and African origins aged between 18 and 64 years, covering all different hair types. For both groups, a significant improvement was observed as early as from D3 in terms of SSSD. This improvement was very significant at D28 (p-value<0.001 for both groups; -71% and -69% for Shampoo A and B). Decrease of total scales was also significant at D28 (p-value<0.001 for both groups; -75% and -68% for Shampoo A and B).

After 28 days, all the subjects presented mild severity of SSD. Erythema levels were significantly reduced from first use for both Shampoo A and B, while improvements in greasiness from D7 onwards were only obvious for Shampoo A.

Moreover, subjects from both treatment groups reported significant improvements in itching, stinging, and burning sensations. Significant improvements for itching were achieved from D3 for Shampoo A and from D7 for Shampoo B. Quality-of-life assessments showed significant improvements for Shampoo A as from D7 and as from D14 for Shampoo B. No significant difference was found between the treatments.

Respondents from both treatment groups rated the various aspects of the hair (hair was soft, glossy, easy to disentangle, voluminous and scalp was less sensitive). Favorable responses ranged between 67.6% (easy to disentangle) and 91.2% (less sensitive scalp) for A, and between 51.7% (gives volume to hair) and 79.3% (less sensitive scalp) for B. Overall, both treatments were very well tolerated without any significant side effects.

FIGURE 1: Illustrative images for Shampoo A on D0, D3 and D28 respectively



FIGURE 2: Illustrative images for Shampoo B on D0, D3 and D28 respectively



FIGURE 3: Results from self-assessment questionnaire

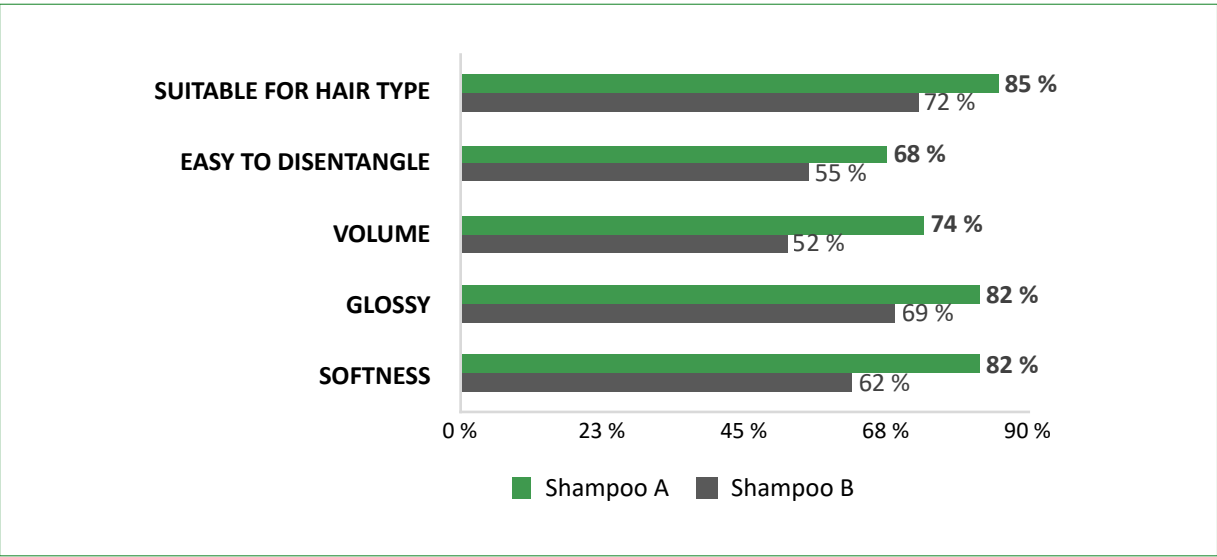


FIGURE 4: Mean difference with respect to baseline in terms of SSSD, by Shampoo

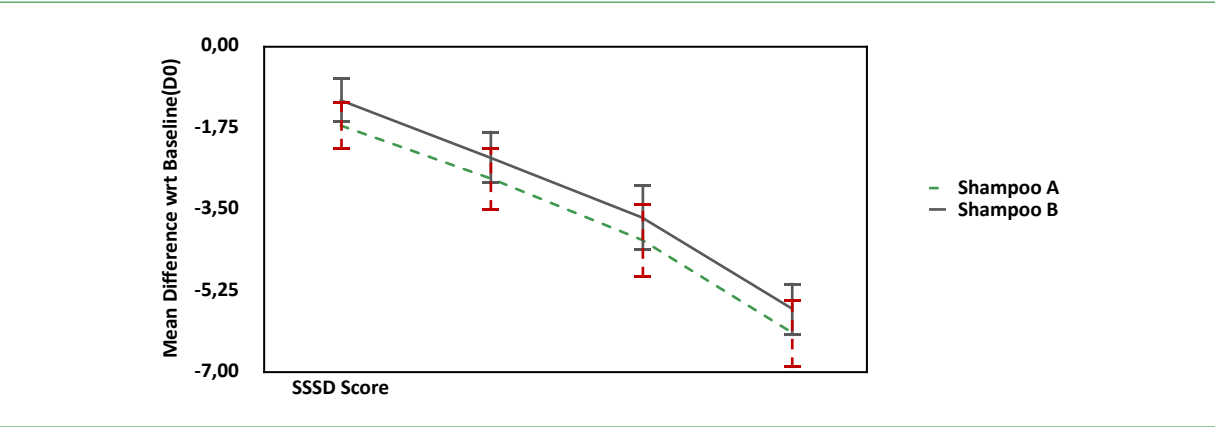


FIGURE 5: Mean difference with respect to baseline in terms of Total scales score (TSS), by Shampoo

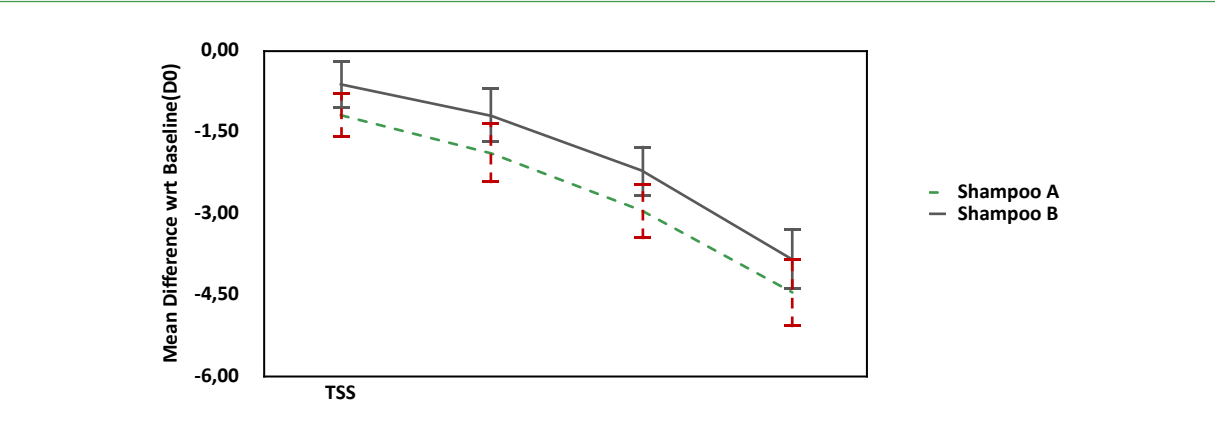
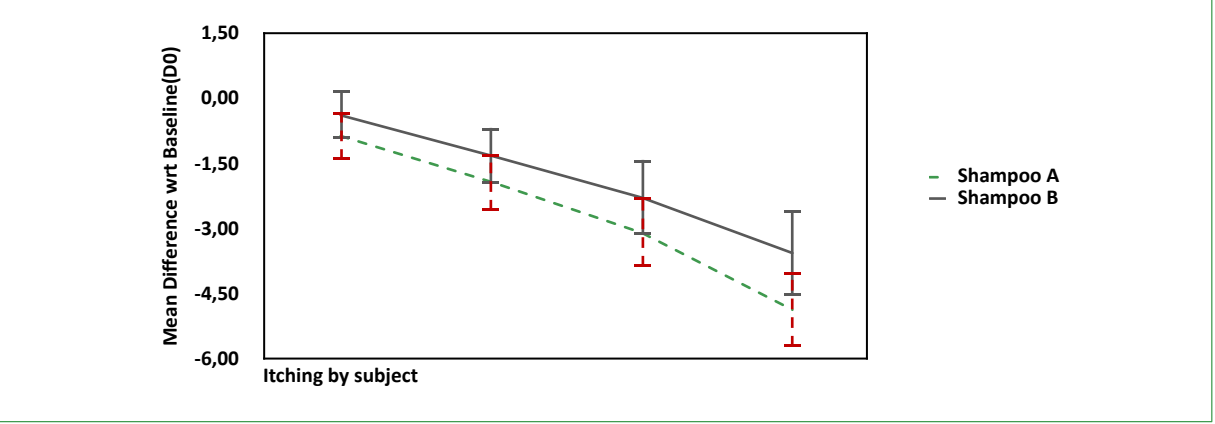


FIGURE 6: Mean difference with respect to baseline in terms of itching, by Shampoo



## 4 CONCLUSION

Shampoo A, composed of 1% selenium disulfide and 1% salicylic acid, is well tolerated and has been shown to be a reliable alternative to a 2% ketoconazole shampoo (B), in terms of efficacy, ease of use and ability to quickly improve itching and quality of life in patients suffering from moderate to severe scalp seborrheic dermatitis.

**References:** 1. World Medical Association. World medical association declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013 [cited 2014 May 20];Vol. 310, No. 20; 2. Buechner SA. Multicenter, double-blind, parallel group study investigating the non-inferiority of efficacy and safety of a 2% miconazole nitrate shampoo in comparison with a 2% ketoconazole shampoo in the treatment of seborrheic dermatitis of the scalp. J Dermatolog Treat. 2014 Jun;25(3):226-31. doi: 10.3109/09546634.2013.782092. Epub 2013 May 21; 3. Sobhan M, Gholampoor G, Firozian F, Mohammadi Y, Mehrpooya M. Comparison of efficacy and safety of atorvastatin 5% lotion and betamethasone 0.1% lotion in the treatment of scalp seborrheic dermatitis. Clin Cosmet Investg Dermatol. 2019;12:267–275. Published 2019 Apr 29. doi:10.2147/CCID.S196412.