A NON-STEROID COMBINATION SHAMPOO VS 1% KETOCONAZOLE SHAMPOO FOR MANAGEMENT OF MILD/MODERATE SEBORRHEIC DERMATITIS OF THE SCALP: RESULTS FROM A RANDOMIZED, INVESTIGATOR BLINDED TRIAL USING CLINICAL AND TRICOSCOPIC EVALUATION

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DISCLOSURE OF COMMERCIAL SUPPORT
The authors don’t have any relevant financial relationships with any commercial interests.
BACKGROUND

• Available treatments for scalp seborrheic dermatitis (SD) are intended to eradicate Malassezia spp. and to reduce inflammation and scaling (1-2)

• Trichoscopy, that allows a magnified view of the scalp (with image capture/storage facility), is a useful tool in the diagnosis and treatment monitoring of inflammatory scalp disorders (3-4)

CLINICAL TRIAL

• 1:1 sequentially randomized, investigator blinded trial

• **Study aim:** to assess **efficacy** and **tolerability** of a **non-steroid combination shampoo** containing 1% piroctone olamine, 1% Vitis vinifera and low concentrations of lactic acid, lactoferrin, and dipotassium glycyrrhizate *versus* 1% ketoconazole shampoo in scalp SD
METHODOLOGY (I)

• **N. of patients:** 20 (9M/11F; age range 16-54 years)

• **Inclusion criteria:** age: >18 yrs, mild to moderate scalp SD; 2-week wash out from topical antimycotics/corticosteroids; 4-week wash out from oral antimycotics/corticosteroids and hormonal therapy

• **Exclusion criteria:** sun exposure; pregnancy
Patients were randomized to **Group A** or **Group B**

<table>
<thead>
<tr>
<th>PATIENTS</th>
<th>TREATMENT</th>
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<tbody>
<tr>
<td><strong>Group A</strong></td>
<td>#10 (4 M, 6 F; mean age: 40.2 years)</td>
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<tr>
<td></td>
<td>Combination shampoo: 1% piroctone olamine, 1% Vitis vinifera and low</td>
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<td>concentrations of lactic acid, lactoferrin, and dipotassium glycyrrhizate</td>
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<tr>
<td><strong>Group B</strong></td>
<td># 10 (5 M, 5 F; mean age: 41.5 years)</td>
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<td>1% ketoconazole shampoo</td>
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**Applications**

3 times/week every other day for 8 weeks
METHODOLOGY (III)

• Efficacy was evaluated by measuring at baseline, week 4 and 8:
  ✓ scaling (by X20 trichoscopy [Hirox, KH-1300, Japan] using a 4-point scale: 0=none; 1=mild; 2=moderate; 3=severe)
  ✓ pruritus (by subject-completed Visual Analogue Scale: 0 mm=no pruritus; 100 mm=severe pruritus)

• Physician Global Assessment (PGA) was assessed at week 8 using a 6-point scale: complete response (> 90% improvement); excellent response (70-90% improvement); moderate response (40-69% improvement); mild response (<40% improvement); no response (no change); worsening

• Tolerability was evaluated at week 8 by a 4-point scale: excellent, good, poor, very poor

• Data were analyzed using Kruskal-Wallis, non-parametric analysis of variance test
RESULTS (I)

• After **4 weeks**, there was a **significant reduction** from baseline of scaling for both groups, while **pruritus** showed a **significant reduction** only for **Group A**

• After **8 weeks**, a **significant reduction** from baseline of **scaling** and **pruritus** for both groups was observed

<table>
<thead>
<tr>
<th>Clinical evaluation</th>
<th>4 WEEKS</th>
<th>8 WEEKS</th>
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<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
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<tr>
<td>Scaling (median*)</td>
<td>from 2.5 to 1.5 (p&lt;0.01)</td>
<td>from 2.5 to 1.5 (p&lt;0.01)</td>
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<tr>
<td>Pruritus (median*)</td>
<td>from 70 to 30 (p&lt;0.01)</td>
<td>from 70 to 60 n.s.^</td>
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*median values = numerical values separating the higher half of a data sample, a population, or a probability distribution, from the lower half.

^ n.s = not significant

**Group A**: non-steroid combination shampoo  
**Group B**: 1% ketoconazole shampoo
Non-steroid combination shampoo: complete response

TRICHOGRAPHIC (X20)

After 4 weeks

After 8 weeks
Non-steroid combination shampoo: complete response
1% ketoconazole shampoo: complete response
RESULTS (II)

- PGA showed a complete response in 90% of cases in both groups.
- Overall, tolerability was rated as excellent (no sign of irritation).

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<th>8 WEEKS</th>
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<tr>
<td></td>
<td>Group A</td>
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<tr>
<td>PGA</td>
<td>Complete response = 90%</td>
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<tr>
<td></td>
<td>Excellent response = 10%</td>
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<tr>
<td>Tolerability</td>
<td>Excellent = 95%</td>
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<td>Good = 5%</td>
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**Group A**: non-steroid combination shampoo  
**Group B**: 1% ketoconazole shampoo
DISCUSSION

• Both shampoos proved to be active for SD after 8 weeks

• **Combination shampoo** was assessed as **better** than 1% ketoconazole shampoo for **pruritus** early in the study at 4 weeks of use. It may represent an **alternative approach** to the management of mild-moderate scalp SD

• **Trichoscopy**, that allowed for a **better assessment** of desquamation, is a promising technique for an advanced evaluation of **treatment response** in scalp diseases