Assessing Patient Satisfaction With Hydrogen Peroxide Topical Solution, 40% (w/w) Treatment of Seborrheic Keratoses on the Face, Neck, and Décodé: Objectives and Design of the Phase 4, Open-Label SK-FAN Study

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SYNOPSIS
Seborrheic keratoses (SKs) are benign cutaneous lesions affecting nearly 84 million individuals in the United States.  
Although SKs are benign growths, these lesions are often cosmetically bothersome to patients, and over 60% of individuals with SKs report taking measures to hide or disguise them from others.  
Recent treatments for SKs involve surgical or ablative modalities such as liquid nitrogen cryosurgery, shave removal, cautery, chemical peels, and laser treatments.  
Recently, a proprietary hydrogen peroxide topical solution, 40% (w/w) HP40 was approved by the US Food and Drug Administration for the treatment of adults with raised SKs.  
The Phase 4, open-label Seborrheic Keratoses of the Face, Neck and Décodé: Objective and Design of the Phase 4, Open-Label SK-FAN study was designed to assess participants’ satisfaction following HP40 treatment on these body regions.

OBJECTIVE
The objective of this presentation is to describe the methodology of the ongoing SK-FAN study.

METHODS
Study Design
The SK-FAN study is a Phase 4, open-label, single-group trial (NCT03487588) that is currently ongoing in 3 sites in the United States.

A schematic of the study design is presented in Figure 1 and the detailed timing of key study procedures is summarized in Table 1. During the study, HP40 is applied to all target lesions at visit 2, then again at visits 5 (day 29) and 6 (day 52), that for target lesions meet the retreatment criterion (see ‘Investigational Product and Treatments’ section). Assessments of participant satisfaction with HP40 treatment take place during visits 2, 3, 4, 6, 8, and 10 (see ‘Subject Satisfaction Assessment’ (SSA) section).

Investigational Product and Treatments

- HP40 is supplied as a single-use applicator to be applied topically to an SK lesion by a healthcare provider
- HP40 is applied to 3 target SKs and up to 4 nontarget SKs during visit 2 (study day 1)
- During treatments, HP40 is applied to each target and nontarget SK for approximately 20 seconds, and each target and nontarget SK may be treated up to 4 times with approximately 60 seconds between each application.

Subject Satisfaction Assessment

- Participants are asked between three levels of satisfaction regarding the study medication treatment experience using the SSA
- There are 3 versions of the SSA to be administered at specified visits as follows:

<table>
<thead>
<tr>
<th>Visit</th>
<th>SSA Version</th>
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<tbody>
<tr>
<td>1</td>
<td>A</td>
</tr>
<tr>
<td>2</td>
<td>A</td>
</tr>
<tr>
<td>3</td>
<td>A or B</td>
</tr>
<tr>
<td>4</td>
<td>B</td>
</tr>
<tr>
<td>5</td>
<td>B</td>
</tr>
<tr>
<td>6</td>
<td>B or C</td>
</tr>
<tr>
<td>7</td>
<td>C</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>At visit 1 prior to application of HP40:</th>
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</thead>
<tbody>
<tr>
<td>1. What prior treatments have you had?</td>
</tr>
<tr>
<td>- None</td>
</tr>
<tr>
<td>- Previous treatments (Select all that apply)</td>
</tr>
<tr>
<td>- Cryotherapy (Freezing)</td>
</tr>
<tr>
<td>- Electrocautery</td>
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<tr>
<td>- Laser therapy</td>
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<tr>
<td>- Microdermabrasion</td>
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<tr>
<td>- Other (please provide)</td>
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<table>
<thead>
<tr>
<th>How often were you satisfied with your prior treatment for your SKs (select one)?</th>
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<tbody>
<tr>
<td>- Not at all</td>
</tr>
<tr>
<td>- Slightly satisfaction</td>
</tr>
<tr>
<td>- Moderately satisfied</td>
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<tr>
<td>- Very satisfied</td>
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<tr>
<td>- Extremely satisfied</td>
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<table>
<thead>
<tr>
<th>What is the likelihood that you will recommend HP40 to a friend/relative?</th>
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<tbody>
<tr>
<td>- Not likely at all</td>
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<tr>
<td>- Slightly likely</td>
</tr>
<tr>
<td>- Moderately likely</td>
</tr>
<tr>
<td>- Very likely</td>
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<tr>
<td>- Extremely likely</td>
</tr>
</tbody>
</table>

Table 1. Timing of Key Study Procedures

| Study Visit | Treatment Day | Days to Visit | Treatment of Target SKs | Study Lesions | Treatment with HP40 | Subject Satisfaction Assessment | Treatment-related Event | Date of First Study Treatment | Target Skin Location
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<thead>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>3–5</td>
<td>HP40 3 target SKs</td>
<td>Neck, face</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>21</td>
<td>HP40 3 target SKs</td>
<td>Neck, face</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>22</td>
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<td></td>
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<td>B</td>
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<tr>
<td>4</td>
<td>3</td>
<td>29</td>
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<td>B</td>
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<td>5</td>
<td>4</td>
<td>52</td>
<td></td>
<td></td>
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<td>B</td>
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<tr>
<td>6</td>
<td>5</td>
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<td></td>
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<td></td>
<td>C</td>
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Table 2. Physician Lesion Assessment Scoring

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Clear no visible SKs</td>
</tr>
<tr>
<td>1</td>
<td>Near-clear visible SK with a surface appearance different from the surrounding skin (not eroded)</td>
</tr>
<tr>
<td>2</td>
<td>Thin visible SK (thickness ≤1 mm)</td>
</tr>
<tr>
<td>3</td>
<td>Thick visible SK (thickness &gt;1 mm)</td>
</tr>
</tbody>
</table>

Table 3. Outcome Measures

- Primary outcome measures:  
  - Question 4 of the end-of-study SSA: "On a scale of 1–5, rate your level of satisfaction with the appearance of your skin treated with HP40?"  
- Secondary outcome measures:  
  - Question 3 of the end-of-study SSA: "On a scale of 1–5, rate your level of satisfaction with the appearance of the target or nontarget SK (if treated in the future) with HP40?"  
- Tertiary outcome measures:  
  - Question 14 and 15 of 4 constructs of confidence, attractiveness, embarrassment, and comfort being photographed  
- Exploratory outcome measures:  
  - Predictors and correlates of SSA ratings  
- Additional analyses:  
  - Correlations between PLLA and SSA scores  
  - Predictors of treatment satisfaction (ie, participant characteristics)

RESULTS

- 41 participants have been enrolled as of 3/15/2023
- Data analyses are currently ongoing with results expected in early 2023
- Images of patients treated with HP40 are available

CONCLUSIONS

- The Phase 4 SK-FAN study is designed to assess patient satisfaction with HP40 treatment for SKs  
- The study will also assess post-treatment satisfaction correlates with efficacy  
- The study is currently ongoing with results expected in early 2019

References


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Disclosures

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