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Seeing the Treatment of Psoriasis in a New Light: A Novel Medical Device Utilizing Localized Coal Tar and Narrowband UVB for Targeted Treatment of Plaque Psoriasis

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INTRODUCTION

Psoriasis is a chronic, immune mediated skin disease that affects 2–4% of the world population.[1] Phototherapy has been a mainstay treatment for psoriasis given its high efficacy, potential to induce remission, and strong safety profile.[1] It is particularly useful in patients who may not be candidates for systemic treatment or biologics. Given the high costs of systemic psoriasis therapies, studies have also shown that phototherapy achieves significant cost savings by replacing or delaying drug-based systemic treatment in patients with moderate to severe disease.[2] However, this modality is often underutilized mainly due to the lack of phototherapy treatment centers across the country.[3] Home phototherapy was designed to fill this treatment gap and allow patients to be treated with phototherapy despite living in areas that may not have a formal treatment facility. Inspired by the Goeckerman regimen, a preliminary pilot study showed that a novel, home phototherapy device utilizing a mobile phone-controlled L.E.D UVB light source and an occlusive hydrogel patch containing coal tar (Figure 1) was superior to control as well as both NB-UVB alone and a coal tar dressing alone. This larger study is designed to further explore the safety and efficacy of this novel modality.

FIGURE 1. UVB light source and an occlusive hydrogel patch containing coal tar.

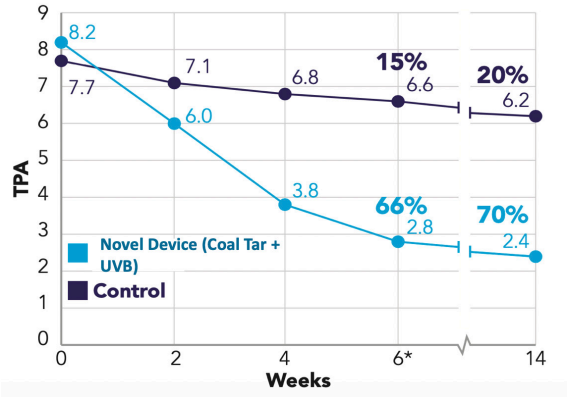
MATERIALS AND METHODS

This was a 30-week, multicenter, investigator-blinded, randomized study that enrolled adults with mild to severe plaque psoriasis (Investigator's Global Assessment (IGA) score 2 to 4 and baseline target plaque assessment (TPA) score 5 to 12) with 2 roughly clinically equal target plaques selected per subject. Plaques were randomized to receive treatment daily with either the UVB plus coal tar dressing vs control (dressing without tar or phototherapy). The first treatment was done in office using a baseline estimated 90% of Minimal Erythema Dose (MED) with increasing dosing each day by 6%. The subjects were required to answer questions about tolerability before subsequent dosing, which impacted the algorithmic dosing schedule. Each plaque was randomly assigned a treatment arm that was unknown to the investigator. The primary endpoint was percent change in TPA score at week 6. Adverse events were assessed at each visit. The modified intent-to-treat efficacy data set using the last observation at the end of treatment compared to baseline is the primary analysis for this study. The study was performed in compliance with Good Clinical Practice and International Conference on Harmonisation guidelines.

RESULTS

In total, 26 patients were enrolled in the study, 3 patients withdrew for non-related medical issues. At week 6, there was a 66% reduction in baseline TPA score vs a 15% reduction in controls (Figure 2). After discontinuation of treatment, there was a 70%, 65%, and 66% reduction in baseline TPA scores at weeks

FIGURE 2. Reduction in target plaque assessment score.



14, 22, and 30, respectively, suggesting a therapeutic effect sustained beyond the treatment period. Approximately one third of patients remained clear at week 22. At week 30, the treatment arm with coal tar and UVB novel medical device's TPA score (2.8) was superior to the control's TPA score (5.1). No significant adverse events were reported, and the most common adverse event was folliculitis.

DISCUSSION

Although Goeckerman therapy has been well studied as an effective therapy for psoriasis, it is not widely used given the travel required, time consuming regimen, and specialized services needed. Here we report a significant reduction in plaque severity as well as a sustained response after a home-based treatment utilizing the two main components of the Goeckerman regimen.

DISCLOSURES

Dr. Jeffrey Sugarman and Evan Anderson own shares of Luma Therapeutics, the company that developed the technology.

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Dr. Jeffrey Sugarman, Principal Investigator, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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