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Improvements in total dermatology life quality index by categories of skin clearance in clinical trials of brodalumab

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Background: We explored health-related quality of life (HRQoL) with respect to degree of skin clearance in the AMAGINE-2/3 trials of brodalumab in patients with moderate to severe plaque psoriasis.

Methods: In this post hoc analysis, HRQoL was monitored by observed total dermatology life quality index (DLQI). Skin clearance was assessed by psoriasis area and severity index (PASI) response for patients who received continuous brodalumab 210 mg every 2 weeks or continuous ustekinumab through week 52.

Results: At baseline, mean (standard error [SE]) DLQI was 14.8 (0.4) in the brodalumab group (n = 326) and 14.9 (0.3) in the ustekinumab group (n = 576). At week 12, mean (SE) DLQI had numerically decreased to 3.0 (0.3) with brodalumab and to 3.9 (0.2) with ustekinumab. Among patients achieving PASI 100 at week 12, mean DLQI was 0 with both brodalumab and ustekinumab. Among patients achieving PASI 75 to <90 and PASI 90 to <100 at week 12, mean DLQI was numerically lower with brodalumab (2.9 and 1.0, respectively) than that with ustekinumab (3.4 and 1.2, respectively). At week 52, mean DLQI among patients who achieved PASI 75 to <90, PASI 90 to <100, and PASI 100 was 2.6, 0.9, and 0 with brodalumab, respectively, and 3.0, 1.0, and 0 with ustekinumab, respectively.

Conclusions: Total DLQI was similar or numerically lower with brodalumab than with ustekinumab at the same level of skin clearance. Achievement of PASI 100 was associated with better total DLQI relative to achievement of PASI 75 to <90 or PASI 90 to <100, regardless of therapy.

Commercial disclosure: 25% sponsored by Ortho Dermatologics.

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Efficacy of brodalumab in total clearance of nail unit psoriasis

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Background: Brodalumab is a fully human anti−interleukin-17 receptor A antagonist efficacious in treating moderate to severe plaque psoriasis. We evaluated the efficacy of brodalumab in patients with nail unit psoriasis in 2 randomized clinical trials (AMAGINE-2/-3), as measured by complete nail clearance.

Methods: Patients were randomized to brodalumab every 2 weeks (q2w), ustekinumab, or placebo. At week 12, patients receiving brodalumab were re-randomized to a brodalumab regimen, patients receiving ustekinumab continued on ustekinumab, and patients receiving placebo switched to brodalumab. Complete nail clearance was defined as total nail psoriasis severity index (NAPSI) score of 0 (sum of individual scores of 0 for pitting, leukonychia, red spots, oil drop, onycholysis, nail bed, splinter hemorrhages, and nail plate crumbling). Data were reported for patients receiving continuous brodalumab 210 mg q2w (n = 104), brodalumab 210 mg q2w after placebo (n = 194), or continuous ustekinumab (n = 179) through 52 weeks using observed data.

Results: At week 12, 7.9% of patients receiving continuous brodalumab, 2.7% of patients receiving brodalumab after placebo, and 2.2% of patients receiving continuous ustekinumab achieved total NAPSI score of 0. At week 52, the percentage of patients receiving continuous brodalumab, brodalumab after placebo, or continuous ustekinumab who achieved total NAPSI score of 0 increased to 63.8%, 53.4%, and 39.1%, respectively. At week 52, the percentage of patients receiving continuous brodalumab with a NAPSI score of 0 for features of nail psoriasis ranged from 44% (pitting) to 92% (red spots).

Conclusions: Brodalumab was associated with complete nail unit clearance at 52 weeks.

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Topical rotational treatment induces dermal collagen changes evidenced by immunohistochemistry and confocal Raman spectroscopy

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Background: A novel topical anti-aging treatment that rotates weekly application of phytol and retinol was previously shown to deliver progressive and sustained benefit over time. Based on in vitro, ex vivo, and in vivo results the efficacy was related to statistically significant increase in epidermal turnover and ECM production versus continuous active application, suggesting superiority of this treatment over standard cosmetic regimen.

Methods: To further evaluate the mechanism of action of rotation of active ingredients in vivo, treatments were evaluated in a human volunteer study. After treatment, two biopsies were obtained from each test/control site. Samples were processed for immunohistochemistry, evaluated by 785 nm laser confocal Raman spectrometry, and compared with several commercially available anti-aging products. Two marketed competitive products were chosen, both with anti-aging benefits. This was a split face randomized comparison study (rotational vs mass and rotational vs prestige). Results Rotational treatment showed a significant increase in pro−collagen I production compared with continuous treatment, which was further highlighted by an additional novel finding of a significant increase in collagen III/I ratio demonstrating the enhanced benefit of rotational treatment. Raman analysis also confirmed presence of retinol and phytol within all three dermal layers, with higher attenuation of peaks accounting for matrix molecules such as collagen in the rotational treatment topical. Rotational products outperformed competitive products with statistical significance as early as week 4.

Conclusions: Rotational treatment shows clinical superiority to continuous treatment of the same active ingredient in the formulation as well as versus standard anti-aging products.

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High adherence and low drop-out in a virtual clinical study of atopic dermatitis through weekly reward-based personalized genetic lifestyle reports

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Background: Clinical trials often suffer from significant recruitment barriers, poor adherence, and drop outs (30% on average), which increase costs and negatively affect trial outcomes. We hypothesised that by making trials virtual, more convenient and reward-based we could 1) recruit nationwide, 2) achieve high adherence, and 3) prevent drop-outs.

Methods: In a siteless, virtual feasibility study, we recruited atopic dermatitis (AD) subjects online. During the 8-week study, subjects used their own smartphones to photograph target AD lesions (https://www.getImagine.io), and completed Patient-Oriented Eczema Measure (POEM) and treatment use questionnaires. In return, subjects were rewarded with personalized lifestyle reports based on their DNA.

Results: 55 subjects were enrolled throughout Denmark, the majority outside the Copenhagen capital region in rural areas with relatively low physician coverage. 53 subjects (96%) completed the study (age 28.4 ± 9.6 y, baseline POEM 14.67 ± 5.55, with mild [6 subjects], moderate [28], or severe [19] AD). 90% of trial data (photos and questionnaires) was collected. Follow up of 41 subjects showed 90.2% had high motivation in the study, ie, would take part again or continue if it had been longer.

Conclusions: We have shown that a virtual trial design enables recruitment with broad geographic reach. In addition, providing personalized genetic reports as a reward results in both high adherence and retention. The next step will be to scale this to a decentralized genome-wide association study of AD with n = 2400 subjects, using emerging technologies to search for novel biomarkers in clinically relevant phenotypes.

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