5th International Conference on

Wound Care, Tissue Repair and Regenerative Medicine

April 15-16, 2022 | Paris, France

Received date: 11-11-2021 | Accepted date: 30-11-2021 | Published date: 15-04-2022

Evaluation of LL-37 in healing of hard-to-heal venous leg ulcers: A multicentric prospective randomized placebo-controlled clinical trial

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Many patients with venous leg ulcers do not reach complete healing with compression treatment alone, which is current standard care. This clinical trial HEAL LL-37 was a phase IIb double-blind, randomized, placebo-controlled study, with the aim to evaluate the efficacy and safety of a new drug LL-37 for topical administration, in combination with compression therapy, in 148 patients suffering from hard-to-heal venous leg ulcers. The study had three arms, consisting of two groups treated with LL-37 at concentrations of 0.5 or 1.6 mg/mL, and a placebo cohort. Patients had a mean age of 67.6 years, a median ulcer duration of 20.3 months, and a mean wound size at the time of randomization of 11.6 cm2. Efficacy analysis performed on the full study population did not identify any significant improvement in healing in patients treated with LL-37 as compared to the placebo. In contrast, a post-hoc analysis revealed statistically significant improvement with LL-37 treatment in several interrelated healing parameters in the subgroup of patients with large target wounds (a wound area of at least 10 cm^2 at randomization), which is a known negative prognostic factor for healing. The study drug was well tolerated and safe in both dose strengths.

In summary, subgroup analysis in this clinical trial provided an interesting observation that the investigated doses of LL-37 could offer a treatment benefit in patients with large ulcers, exigently warranting further clinical investigations to validate the treatment outcome in this patient group.

Recent publications

1. Mahlapuu M, Sidorowicz A, Mikosinski J, et al. Evaluation of LL-37 in healing of hard-to-heal venous leg ulcers: A multicentric prospective randomized placebocontrolled clinical trial. Wound Repair Regeneration (2021) 29(6):938-950.

2. Kurhe Y, Caputo M, Cansby E, Xia Y, Kumari S, Howell BW, Marschall HU, Mahlapuu M. Antagonizing STK25 signaling suppresses the development of hepatocellular carcinoma through targeting metabolic, inflammatory, and pro-oncogenic pathways. Cellular and Molecular Gastroenterology and Hepatology (2021). Accepted for publication.

3. Caputo M, Kurhe Y, Kumari S, Cansby E, Amrutkar M, Scandalis E, Booten SL, Ståhlman M, Borén J, Marschall HU, Aghajan M, Mahlapuu M. Silencing of STE20-Type Kinase MST3 in Mice with antisense oligonucleotide treatment ameliorates diet-induced non-alcoholic fatty liver disease. FASEB J. (2021) 35(5):e21567.

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