

■ ABSTRACT

Evaluation of lyophilized human amnion/chorion membrane (LHACM) in the management of nonhealing diabetic foot ulcers: an interim analysis of the CAMPAIGN trial

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Abstract

Background: Diabetic foot ulcers (DFUs) are chronic wounds that contribute significantly to morbidity, mortality, and healthcare costs. Despite current standard-of-care (SOC) approaches, healing rates re-main suboptimal, emphasizing the urgent need for innovative and cost-effective treatment options.

Methods: An interim analysis of this multicenter, prospective, randomized controlled platform clinical trial evaluated the efficacy of multiple lyophilized human amnion/chorion membrane (LHACMs) with SOC versus SOC alone. The primary endpoint was percentage of target ulcers achieving complete wound closure in 12 weeks, defined as 100% re-epithelialization without drainage for two consecutive weeks, confirmed by blinded independent review.

Results: The statistical analysis revealed that the treatment arm improved full wound closure at 12 weeks over SOC by 2.6 (credible interval: 0.81 – 5.0) in terms of relative. The estimated probability of complete wound closure under SOC was 23% (6.5%–42%), compared with 47% (37%–59%) under the treatment arm. This corresponds to a posterior absolute difference of 24% (4%–43%). This suggests a posterior probability advantage of 98.5% for LHACM.

Conclusion: The interim analysis revealed that the placental membranes products trended to-ward superiority over SOC. Bayesian posterior estimates indicated 98.5% higher probabilities of wound closure and improved healing trajectories in the treatment group. These interim data provide early evidence of clinical benefit, subject to confirmation with full trial completion.