

■ ABSTRACT

Evaluation of cellular, acellular, and matrix-like products in the management of nonhealing venous leg ulcers: an interim analysis of STABLECAMP

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Abstract

Background: Venous leg ulcers (VLU), a painful and debilitating condition, adversely affect patient quality of life and impose a burden on health care systems across the globe. Existing standard of care (SOC) yields limited healing success, emphasizing the need for new and more effective treatment strategies.

Methods: An interim analysis of this multicenter, prospective, randomized controlled modified platform clinical trial evaluated the efficacy of cellular, acellular, and matrix-like products (CAMPs) 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: In Intent-To-Treat (ITT), dual layer amniotic membrane allograft (DLAG) with SOC arm achieved a 50% closure rate versus 16.7% with SOC alone, an 33.3% absolute gain that was statistically significant ($n=20$, 95% CI 5.6% to 55.8%, $p=0.018$, $\alpha=0.05$). All other treatment groups were not significant in the ITT population. All treatment groups were not significant in the Per Protocol (PP) population. Additionally, the percent area reduction (PAR) from TV-1 to TV-13 measured weekly with digital photographic planimetry, using an imaging device, and physical examination were analyzed. For ITT, DLAG + SOC outperformed SOC on both average and median wound-area reduction. For PP, DLAG + SOC outperformed SOC on both average and median wound-area reduction. Demographic summary statistics were analyzed to determine randomized baseline balance across groups, which was achieved with no statistically significant differences between groups at the time of interim analysis.

Conclusion: The interim analysis revealed that the placental membrane products trended to-wards superiority over SOC. The statistical significance in the ITT population for DLACG suggests that this product may be superior to SOC.

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