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ABSTRACT

Evaluation of human placental-based cellular, acellular and matrix-like products (CAMPs) in the management of nonhealing diabetic foot ulcers: an interim analysis of the CAMPSTIM clinical trial

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Abstract

Background: Diabetic foot ulcers (DFUs) are characterized by chronicity and poor healing, leading to elevated morbidity, mortality, and healthcare expenditures. The suboptimal efficacy of standard-of-care (SOC) underscores the demand for innovative, cost-efficient treatments.

Methods: An interim analysis of this multicenter, prospective, randomized, controlled, modified platform trial evaluated efficacy of multiple cellular, acellular, and matrix-like products (CAMPs) plus SOC versus SOC alone in achieving complete closure of hard-to-heal DFUs in 12-weeks.

Results: Baseline demographics and clinical characteristics were similar between groups. In intent-to-treat (ITT), the fenestrated dehydrated complete human placental membrane (dCHPM) allograft (Relese®) plus SOC arm (n=53) achieved 11.6% absolute gain in closure rate treatment effect vs. SOC alone (n=60) (95% confidence interval (CI) [-3.7%, 26.8%], p=0.14). In per protocol (PP), the Relese® plus SOC arm (n=38) achieved 16.8% absolute gain in closure rate treatment effect vs. SOC alone (n=44), trending towards statistical significance (95% CI [-3.2%, 35.4%], p = 0.10). The relative risk of complete closure for Relese® plus SOC was 1.70 (95% CI [0.84, 3.45]) in ITT and 1.74 (95% CI [0.89, 3.40]) in PP,

corresponding to 70% (ITT) and 74% (PP) higher relative closure probabilities compared to SOC alone. Given the superior treatment arm closure rate, treatment effect is expected to strengthen and reach statistical significance upon enrollment completion. Additionally, percent area reduction (PAR) over 12-weeks was analyzed. For ITT and PP, treatment group outperformed SOC (ITT; median SOC: 47.1%, Relese®: 71.1%). Safety was comparable between groups, with no product-related adverse events reported.
Conclusion: This interim analysis demonstrates favorable treatment effects for fenestrated dCHPM allografts. Based on closure rate and PAR analyses, continued enrollment is warranted, and the trial will proceed to completion.

Conflicts of interest: The authors declare no conflicts of interest.
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