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ABSTRACT

A multicenter, prospective randomized controlled modified dual platform trial evaluating several cellular, acellular, and matrix-like products (CAMPs) and standard of care versus standard of care alone in the management of nonhealing diabetic foot ulcers and venous leg ulcers (TIGERCAMP)

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Abstract

Aim: To determine the between-arm difference in the proportion of subjects achieving complete closure of nonhealing diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) with multiple CAMPs plus SOC versus SOC alone over 12 weeks using a modified dual platform (Matriarch) trial design.

Methods: This multicenter, prospective, randomized controlled trial employs a modified plat-form design. Patients with, nonhealing DFUs or VLUs will be randomized to receive either SOC alone or SOC in combination with one of multiple CAMPs. The initial phase will evaluate two CAMPs for each ulcer type: amnion chorion amnion placental allograft (ACA; ACAPatch™, Tiger Wound Care Medical, LLC, Conshohocken, PA, USA) and full-thickness placental membrane allograft (FT; caregraFT™, Tiger Wound Care Medical, LLC, Conshohocken, PA, USA). However, the modified platform design allows for subsequent inclusion of additional CAMPs. The primary endpoint is complete wound closure within 12 weeks. Secondary endpoints include time to closure, percentage wound area reduction, number of adverse events, change in patient reported pain, and average number of placental allografts used. Exploratory endpoints include change in patient quality of life, percent of target ulcers achieving complete closure for patients 65 years of age or older, and change in functional ambulation.

Results: Upon completion of the trial, results will be reported in accordance with the study protocol. Separate pooled analyses for DFUs and for VLUs will be published. Additionally, a master publication for all pooled product arms vs pooled SOC arms will be completed.

Conclusion: This trial is anticipated to provide efficacy data on multiple CAMPs used as adjuncts to SOC, thereby

strengthening evidence-based practice in DFU and VLU management. The modified platform design provides a flexible and efficient model to evaluate multiple interventions within a single trial.

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