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ABSTRACT

Evaluating several cellular, acellular, and matrix-like products (CAMPs) and standard of care in the management of non-healing pressure ulcers using matched controls: a randomized controlled modified platform trial

Thomas Serena[1] MD | **Brianna Tramelli**[1] | **Emily King**[1] MS | **Ekaterina Chashnikova**[1]

[1]SerenaGroup, Inc., Cambridge, MA

Correspondence: Brianna Tramelli (btramelli@serenagroups.com)

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Abstract

Aim: To determine the between-arm difference in the proportion of subjects achieving complete closure of nonhealing pressure ulcers with multiple CAMPs plus SOC versus matched SOC (mSOC) over 20 weeks using a modified platform trial design.

Methods: This randomized controlled modified platform trial is designed to assess the efficacy of cellular, acellular, and matrix-like products alongside SOC in the closure of pressure ulcers. The trial will initially review two CAMPs: amnion chorion amnion placental allograft (ACA; ACApatch™, Tiger Wound Care Medical, LLC, Conshohocken, PA, USA) and full-thickness placental mem-brane allograft (FT; caregraFT™, Tiger Wound Care Medical, LLC, Conshohocken, PA, USA). However, the modified platform design allows for additional products to be included with protocol amendment. All enrolled patients will be matched on key demographic and clinical factors to ensure group comparability, minimize bias, and strengthen the validity of care effect comparisons. The primary endpoint is the percentage of target ulcers achieving complete wound closure over 20 weeks. Secondary endpoints include time to closure, percentage wound area reduction, number of adverse events, change in quality-of-life, and average number of placental allografts used. Exploratory endpoint is percentage of target ulcers achieving complete wound closure for subjects 65 years of age or older.

Results: At the conclusion of the trial, study findings will be reported in accordance with the approved protocol.

Conclusion: This trial is anticipated to provide efficacy data on multiple CAMPs used in concurrence with SOC, improving evidence-based practice for pressure ulcer management. The modified platform design provides a flexible model to evaluate multiple interventions within a single trial. The use of mSOC as the control arm allows for unbiased comparisons and enhances reliability of observed treatment effects.

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