Miro3D Randomized Controlled Trial (RCT)

NCT07347106

Status	RECRUITING
Phase	Not Applicable
Sponsor	Washington University School of Medicine
Enrollment	70 participants

Key Eligibility Criteria

Inclusion (9)

- Men or women 18-90 years of age at enrollment.
- Ability to sign consent by subject or LAR.
- Wounds in one of the two arms:
- A. Soft tissue wounds with a minimum size of 1 cm x 1 cm surface area and a maximum size of 40 cm L x 20 cm W x 5 cm D, resulting from either post-fasciotomy or post-NSSTI, including the pelvis with the lower extremity. Fasciotomies must have undergone complete debridement and, in the opinion of a trial investigator, be appropriate for wound healing but not ready for primary closure at randomization.
- B. Chronic, complex pressure ulcers classified as Stage III or higher, located in the decubitus or ischial region, that have not achieved at least a 50% reduction in ulcer area despite receiving documented SOC treatment for a minimum of four (4) weeks, with confirmed patient compliance.

... and 4 more (see full listing online)

Exclusion (13)

- Subjects who meet any of the following criteria will be excluded from trial participation:
- The PAR of the pressure ulcer arm has reduced by 50% or more after four (4) weeks of SOC.
- Wounds with active invasive infection not yet controlled in the opinion of a trial investigator.
- Wounds with vascular insufficiencies requiring revascularization.
- Trial investigator deems the subject has no meaningful wound healing potential (e.g., advanced cancer, severe malnutrition) and/or has conditions that seriously compromise the subject's ability to complete the trial or a known history of non-adherence to medical care.

... and 8 more (see full listing online)

Locations (1 total)

Washington University School of Medicine, St Louis, Missouri, United States