

Miro3D Wound Matrix Study for Diabetic Foot Ulcers and Wound Healing

NCT06939686

Status	RECRUITING
Phase	Not Applicable
Sponsor	Reprise Biomedical, Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (10)

- Must be at least 18 years of age and capable of providing informed consent.
- Must have a full- or partial-thickness Wagner Grade 1 ulcer or wound on the foot; if involving the malleolus, no more than 50% of the wound may be above the midpoint of the medial malleolus.
- Index wound/ulcer must be between 1 cm² and 20 cm² post-debridement.
- Wound/ulcer must have been present for at least 4 weeks prior to screening.
- Adequate circulation must be documented by one of the following: ABI between 0.7-1.2, TBI e 0.7, TCPO2 e 40 mmHg, or triphasic/biphasic Doppler waveforms.

... and 5 more (see full listing online)

Exclusion (14)

- Index wound/ulcer has reduced e30% after two weeks of SOC from screening to baseline.
- Poorly controlled diabetes (HbA1c e 12%).
- Active, untreated or uncontrolled osteomyelitis.
- Malignancy or vasculitis at the wound site.
- Undergoing chemotherapy.

... and 9 more (see full listing online)

Locations (3 total)

West Boca Center for Wound Healing, Coconut Creek, Florida, United States
Barry University Clinical Research, Tamarac, Florida, United States
Icahn School of Medicine at Mount Sinai, New York, New York, United States