Matrion Decellularized Placental Membrane Versus Conventional Wound Management in Subjects With Diabetic Foot Ulcers

NCT07116876

Status	RECRUITING
Phase	Not Applicable
Sponsor	LifeNet Health
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (17)

- Be male or female and aged between 21 and 80 years at the time of informed consent
- Have a diagnosis of Type I or Type II diabetes as defined by the American Diabetes Association and have been on a stable anti-diabetic treatment regimen for at least 30 days before the baseline visit.
- Have full-thickness wound of the lower extremity, below the ankle
- Have a single target ulcer
- Have a wound with an area greater than or equal to 1cm2 and less than 25 cm2 with a depth less than or equal to 9 mm

... and 12 more (see full listing online)

Exclusion (20)

- Be pregnant or lactating
- Subjects with a target wound \<30 days old at Screening whose wound area has decreased in size e50% between the Screening and Baseline Visits (assessed at Baseline/Visit 2)
- Have a circulating hemoglobin A1c exceeding 12% within 90 days of the Screening Visit (assessed at Screening/Visit 1 for subjects with labs collected \<30 days of screening; assessed at Baseline/Visit 2 for subjects with labs collected at screening)
- Have a serum creatinine concentration of 3.0 mg/dL or greater within 30 days prior to screening (assessed at Screening/Visit 1 for subjects with labs collected \<30 days of screening; assessed at Baseline/Visit 2 for subjects with labs collected at screening)
- Have a sensitivity to either of the following antibiotics: lincomycin, gentamicin, polymyxin B, or vancomycin

... and 15 more (see full listing online)

Locations (18 total)

Compass Medical Research Center, Tucson, Arizona, United States
Bay Area Foot Care, Castro Valley, California, United States
Limb Preservaion Platform, Inc., Fresno, California, United States
... and 15 more locations