Clinical Trial Evaluating an Amnion Membrane Allograft for Use in the Management of Non- Healing Diabetic Foot Ulcers Versus Standard Of Care

NCT06767501

Status	RECRUITING
Phase	Not Applicable
Sponsor	Skye Biologics Holdings, LLC
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (12)

- Subjects must be at least 18 years of age or older.
- Subjects must have a diagnosis of type 1 or 2 Diabetes mellitus.
- At randomization subjects must have a target diabetic foot ulcer with a minimum surface area of 1.0 cm2 and a maximum surface area of 10.0 cm2 measured post debridement with manual measurement.
- The target ulcer must have been present for a minimum of 4 weeks and a maximum of 52 weeks of standard of care prior to the initial screening visit.
- The target ulcer must be located on the foot with at least 50% of the ulcer below the malleolus.

... and 7 more (see full listing online)

Exclusion (19)

- Target ulcers located on the plantar aspect of the foot must be offloaded for at least 14 days prior to randomization.
- The subject must consent to using the prescribed off-loading method for the duration of the study.
- The subject must agree to attend the weekly study visits required by the protocol.
- The subject must be willing and able to participate in the informed consent process.
- A subject known to have a life expectancy of \< 6 months is excluded.

... and 14 more (see full listing online)

Locations (1 total)

Professional Education and Research Institute, Roanoke, Virginia, United States