

Trial Assessing the Efficacy of Human Placental Membrane Products and Standard of Care Versus Standard of Care Alone in the Management of Nonhealing Diabetic Foot Ulcers and Venous Leg Ulcers

NCT07089602

Status	RECRUITING
Phase	Phase 4
Sponsor	BioLab Holdings
Enrollment	650 participants

Key Eligibility Criteria

Inclusion (19)

- The potential subject must be at least 18 years of age or older.
 - The potential subject must have a diagnosis of type 1 or 2 Diabetes mellitus.
 - At enrollment, the potential subject must have a target ulcer with a minimum surface area of 1.0 cm² and a maximum surface area of 20 cm² measured post debridement with the eKare inSight® imaging device.
 - The potential subject must have a target ulcer that has been present for a minimum of 4 weeks of standard of care, prior to the initial screening visit.
 - The potential subject must have a target ulcer located on the foot with at least 50% of the ulcer below the malleolus.
- ... and 14 more (see full listing online)

Exclusion (42)

- The potential subject must consent to using the prescribed offloading method for the duration of the study.
 - The potential subject must agree to attend the weekly study visits required by the protocol.
 - The potential subject must be willing and able to participate in the informed consent process.
 - The potential subject is known to have a life expectancy of < 6 months.
 - The potential subject's target ulcer is not secondary to diabetes.
- ... and 37 more (see full listing online)

Locations (1 total)

Center for Foot and Ankle Disorders, Philadelphia, Pennsylvania, United States