

Evaluating Intact Fish Skin Graft and Standard of Care Versus Standard of Care Alone in Nonhealing Venous Leg Ulcers

NCT06693570

Status	RECRUITING
Phase	Phase 4
Sponsor	Kerecis Ltd.
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (9)

- Subjects must be at least 18 years of age or older.
- Subjects must have a nonhealing venous leg ulcer present for a minimum of 4 weeks and cannot have received more than 52 weeks of high-level compression prior to the initial screening visit.
- No visible signs of healing objectively, less than 40% reduction in wound size in the last 4 weeks.
- At randomization, subjects must have a target ulcer with a minimum surface area of 1 cm² and a maximum surface area of 25 cm² measured post-debridement.
- The affected limb must have adequate perfusion confirmed by vascular assessment. Any of the following methods performed within 3 months of the first screening visit are acceptable:
... and 4 more (see full listing online)

Exclusion (28)

- Subjects must have a Functional Ambulatory Category Score (FACS) of 3 or greater.
- Subjects must consent to using the prescribed compression method for the duration of the study.
- Subjects must agree to attend the weekly study visits required by the protocol.
- Subjects 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.
... and 23 more (see full listing online)

Locations (1 total)

Serena Group- Monroeville, Monroeville, Pennsylvania, United States