Dermacyte® Amniotic Wound Care Liquid for the Treatment of Non-Healing Venous Stasis Ulcers

NCT04647240

Status	RECRUITING
Phase	Phase 2
Sponsor	Merakris Therapeutics
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (21)

- Subjects who voluntary give written informed consent to participate in study
- Males and female subjects aged 18 to 75 years inclusive at Screening (date the subject provides written informed consent to participate in study) for Part 1 only
- Males and female subjects aged 18 to 80 years inclusive at Screening (date the subject provides written informed consent to participate in study) for Part 2 only
- Subjects must have a full thickness ulcer that meets the following criteria:
- Ulcer surface area \> 1 cm2 and \< 25 cm2

... and 16 more (see full listing online)

Exclusion (18)

- Subject must not be currently receiving topical antimicrobials and ulcer must not be infected as determined by clinical assessment (e.g. odor, color, visual appearance) rather than culture.
- Ulcer must not have exposed bone, tendon, or ligament.
- Subject must not have another ulcer within 3 cm from the ulcer receiving investigational treatment.
- Female subjects who are pregnant, lactating, or planning to become pregnant during the study.
- Subjects actively receiving or received a skin graft substitutes within 30 days prior to Baseline.

... and 13 more (see full listing online)

Locations (9 total)

Compass Medical Research Center, Tucson, Arizona, United States
Center for Clinical Research, Inc., Castro Valley, California, United States
Limb Preservation Platform, Inc., Fresno, California, United States
... and 6 more locations