

Modified Platform Trial Assessing Multiple CAMPs and SOC vs SOC Alone in the Treatment of Hard-to-Heal DFUs

NCT06449638

Status	RECRUITING
Phase	Not Applicable
Sponsor	StimLabs
Enrollment	272 participants

Key Eligibility Criteria

Inclusion (11)

- At least 18 years of age or older.
- Diagnosis of type 1 or 2 Diabetes mellitus.
- At enrollment, target ulcer with a minimum surface area of 1.0 cm² and a maximum surface area of 25.0 cm² measured post debridement with the MolecuLight® Imaging Device.
- 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 6 more (see full listing online)

Exclusion (24)

- Target ulcers located on the plantar aspect of the foot must be offloaded for at least 14 days prior to enrollment.
- 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.

... and 19 more (see full listing online)

Locations (5 total)

SerenaGroup Omaha Research Center, Omaha, Nebraska, United States
Wound Care of Tulsa, Tulsa, Oklahoma, United States
SerenaGroup Research South, Jefferson Hills, Pennsylvania, United States
... and 2 more locations