INNOVEN: Efficacy of Porcine Placental Extracellular Matrix Plus Standard of Care (SOC) Versus SOC Alone

NCT06606210

Status	RECRUITING
Phase	Not Applicable
Sponsor	ConvaTec Inc.
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (9)

- Subjects must be at least 21 years of age or older.
- 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 target ulcer must have been 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 improvement in the four weeks prior to randomization: less than 40% reduction in wound size over the 4 weeks prior to randomization.
- 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 (22)

- 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 target ulcer exhibits signs or symptoms consistent with clinical infection, requiring topical antibiotic or antimicrobial agents or systemic antibiotic therapy, or there is cellulitis in the surrounding skin.
- The target ulcer exposes tendon or bone.

... and 17 more (see full listing online)

Locations (1 total)

Three Rivers Wound and Hyperbaric Center, North Port, Florida, United States