

Study Assessing Complete Wound Healing by Comparing Surgenex® PelloGraft in Treating DFU and SanoGraft® in Treating VLU to SOC

NCT06515093

Status	RECRUITING
Phase	Not Applicable
Sponsor	Surgenex
Enrollment	180 participants

Key Eligibility Criteria

Inclusion (7)

- Subject is at least 18 years of age
- Diabetic Foot Ulcer Only - Subject has diagnosed Type 1 or Type 2 diabetes
- Subject's wound is located on foot or ankle (DFU) or leg (VLU)
- Subject has diabetic foot ulcer ≥ 1.0 cm² and ≤ 25 cm² OR venous leg ulcer ≥ 1.0 cm² and ≤ 50 cm²
- Subject has adequate circulation to affected extremity with TcPO₂ results of ≥ 40 mm Hg on the dorsum of the affected foot or ABI results ≥ 0.7 and ≤ 1.2 or Great Toe Pressure ≥ 50 mmHg
- ... and 2 more (see full listing online)

Exclusion (11)

- Subject is pregnant
- Subject with diagnosed diabetes has HbA_{1C} ≥ 12 within 3 months Prior to randomization
- Subject has $\geq 30\%$ reduction in wound size after 2-week run-in period
- Subject has active infection, undrained abscess, or critical colonization of the wound with bacteria
- Subject has osteomyelitis or joint capsule on investigator's exam or radiographic evidence or bone culture, histology, x-ray changes or MRI
- ... and 6 more (see full listing online)

Locations (2 total)

ILD Research, Vista, California, United States
Tulsa Wound Center, Tulsa, Oklahoma, United States

<https://clinicaltrials.gov/study/NCT06515093>

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