A Double Blind Study Performed to Evaluate the Efficacy and the Safety of EscharEx in Debridement of VLU (VALUE)

NCT06568627

Status	RECRUITING
Phase	Phase 3
Sponsor	MediWound Ltd
Enrollment	216 participants

Key Eligibility Criteria

Inclusion (6)

- Men or women, older than 18 years of age,
- Patients with a VLU (determined by medical history, physical examination, and a documented ultrasound scan demonstrating venous insufficiency),
- Wound is present for at least 4 weeks but no longer than 1 year,
- The adherent necrotic/thick slough/fibrin non-viable tissue area, assessed following wound cleansing with wet gauze and either sterile saline or water and mild soap, at least 50% of the wound area (assessed by clinical evaluation),
- Target wound surface area is in the range of 2-25 cm2 (assessed by eKare inSightTM),

... and 1 more (see full listing online)

Exclusion (25)

- Wound size that has decreased by \> 20% after 7 (+3/-1) days of the screening period,
- Patients with more than one leg ulcer, on the leg of the target wound, with an area greater than or equal to 2 cm2, that are between 2cm and 5cm away from the edge of the target wound,
- Signs of clinical infection of the wound or peri-wound, including purulent discharge, deep-tissue abscess, erysipelas, cellulitis, etc.,
- Severely damaged skin (e.g. abrasion, erosion, exfoliation) extending \>2 cm around the wound's edge,
- Presence of gangrene, signs of systemic infection, sepsis, or osteomyelitis during screening phase,

... and 20 more (see full listing online)

Locations (25 total)

Limb Preservation Platform, Inc, Fresno, California, United States
Angel City Research,Inc, Los Angeles, California, United States
Center for Clinical Research INC, San Francisco, California, United States
... and 22 more locations