

A Study of XSTEM-VLU in Patients With Difficult-to-heal Venous Leg Ulcers

NCT05549609

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Xintela AB
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (6)

- Written informed consent for participation in the study
- Male or female patient aged ≥18 years
- BMI ≥18.5 and ≤40.0 kg/m²
- Lower leg wound due to venous insufficiency
- Target wound has failed to heal despite standard wound care for a minimum of 6 weeks

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

Exclusion (8)

- Signs or symptoms of clinically significant ongoing infection in the target wound requiring anti-microbial treatment
- History of autoimmune disease, such as but not limited to systemic lupus erythematosus, Addison's disease, Crohn's disease and type I diabetes mellitus
- B-HbA1C value ≥52 mmol/mol
- Plaque psoriasis or any other skin disease that could interfere with the outcome of the study
- Arterial insufficiency

... and 3 more (see full listing online)

Locations (4 total)

Clinical Trial Center (CTC), Gothenburg, Sweden
Burn Centre, Linköping University Hospital, Linköping, Sweden
Clinical Research Unit, Lund, Sweden
... and 1 more locations