

Trial to Evaluate Cyclical Topical Wound Oxygen Therapy in the Treatment of Chronic Venous Leg Ulcers

NCT06754735

Status	RECRUITING
Phase	Phase 4
Sponsor	AOTI Ltd.
Enrollment	212 participants

Key Eligibility Criteria

Inclusion (11)

- Adults e 18 years and able to provide written informed consent
 - Patients who have a chronic venous leg ulcer (VLU) below the knee at or above the malleolus determined to be due to underlying venous disease
 - Venous reflux e 500 mil sec/superficial or 1 sec/deep or venous mapping after interventions following a vascular procedure
 - VLU of e 1.5cm² and d 50cm² after debridement at study enrolment i.e. Screening visit
 - *Cluster wounds where the sum of the full thickness ulcer area must be d 50cm²
- ... and 6 more (see full listing online)

Exclusion (19)

- • Known allergy to any of the protocol-stipulated treatments, or non-tolerance of multilayer, multicomponent compression therapy
 - Acute thrombophlebitis or Deep Vein Thrombosis (DVT) and within three months preceding study entry
 - Subject awaiting venous ablation or is less than 30 days post ablation
 - Surgery during three months prior to study entry (such as abdominal, gynecological, hip or knee replacement)
 - Wound etiology of uncertain origin or history or prior diagnosis of Systemic Lupus Erythematosus, Burger's Disease, Pyoderma Gangrenosum or other inflammatory ulceration, vasculitis
- ... and 14 more (see full listing online)

Locations (1 total)

Vascular Institute of New York, New York, New York, United States