

Clinical Study to Evaluate the Effectiveness and Health Economics of a Novel Portable Non-Pneumatic Active Compression Device (NPCD) for Lymphedema/Phlebolymphe^dema

NCT06418282

Status	RECRUITING
Phase	Not Applicable
Sponsor	Koya Medical, Inc.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (4)

- Males and females e 18 years of age
- Capable and willing to sign the informed consent and deemed capable of following the study protocol
- Subjects must have a diagnosis of unilateral or bilateral lower extremity edema or lower extremity lymphedema/phlebolymphe^dema as a consequence of chronic venous insufficiency
- Subjects who have medical clearance using diagnostic confirmation through venous duplex to rule out DVT and superficial/deep reflux

Exclusion (21)

- Inability or unwillingness to participate in all aspects of study protocol and/or inability to provide informed consent
- Individuals with a history or presence of a systemic disorder or condition that could place the subject at increased risk from sequential compression therapy
- Subjects must not have any diagnosed cognitive or physical impairment that would interfere with the use of the device
- Non-ambulatory individuals
- Female: BMI \> 34 (5'4", 200 lbs.)
- ... and 16 more (see full listing online)

Locations (1 total)

Glenn Jacobowitz, New York, New York, United States