

The Tetherx Natural Vascular Scaffolding (NVS) Procedure for Treating Patients with Atherosclerosis of the Femoropopliteal Artery

ACTRN12611000897965

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Tetherx, Inc.
Enrollment	30 participants

Plain Language Summary

This study is testing a new treatment for blocked arteries in the leg called the Tetherx Natural Vascular Scaffolding (NVS) procedure. Blocked leg arteries cause leg pain when walking (claudication) or even pain at rest. The procedure uses a special solution to support the artery from the inside without a metal stent. Participants will be monitored for 12 months for safety and effectiveness.

You may be eligible if:

- You are between 18 and 85 years old
- You have leg pain from artery blockage (claudication or rest pain) rated Rutherford category 2, 3, or 4
- You can walk without assistance
- You have a documented low ankle-brachial index (poor blood pressure in the foot compared to the arm)

You may NOT be eligible if:

- Your life expectancy is less than 12 months
- You have had a stroke or heart attack in the last 3 months
- You are allergic to heparin, aspirin, or the solution used in the procedure
- You have severe kidney problems (creatinine above 2.5 mg/dL)
- You have had a previous lower-limb amputation (other than a toe)
- You are pregnant or planning to become pregnant

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (7)

- I1 Age > 18 years and < 85 years
- I2 Subject or subject's legal representative have been informed of the nature of the study, agrees to participate and has signed an EC approved consent form
- I3 Female subjects of childbearing potential have a negative pregnancy test at 7 days before the procedure and are willing to use a reliable method of birth control for the duration of study participation
- I4 Subject understands the duration of the study and its follow up visit requirements
- I5 Subject has documented claudication or ischemic rest pain in the target limb prior to the study procedure with documented Rutherford category 2, 3, or 4
- ... and 2 more (see full listing online)

Exclusion (12)

- E1 Life expectancy < 12 months (in the Investigator's opinion)
- E2 Debilitating cerebrovascular accident (CVA) or ST Segment Myocardial Infarction (STEMI) within the 3 months prior to enrollment

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12611000897965>

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- I4 Known allergies or sensitivities to heparin, aspirin, other anti-coagulant/antiplatelet therapies, and/or the NVS vascular polyethylene glycol (PEG) solution
 - I5 Allergy to contrast media that cannot be adequately pre-treated prior to procedure
- ... and 7 more (see full listing online)

Locations (1 total)

New Zealand