Temsirolimus Adventitial Delivery to Improve ANGioplasty and/or Atherectomy Revascularization Outcomes Below the Knee

NCT04433572

Status	RECRUITING
Phase	Phase 3
Sponsor	Mercator MedSystems, Inc.
Enrollment	250 participants

Key Eligibility Criteria

Inclusion (20)

- Pre-procedural:
- Participant has signed and dated informed consent, is capable of understanding the nature, significance and implications of the clinical trial, and is willing to comply with all study procedures and follow-up visits for the duration of the study.
- Participant is male or female, aged 18 years or older.
- If participant is female and of reproductive potential: agreement to use a highly effective contraception (abstinence is acceptable) for at least 90 days after study treatment.
- Participant has severe claudication (Rutherford 3) or chronic limb-threatening ischemia (CLTI) (Rutherford 4-5) in the Target Limb.

... and 15 more (see full listing online)

Exclusion (41)

- Pre-procedural:
- Participant is already enrolled in another clinical study of systemic or local vascular drug therapy or a vascular device study that has not completed its primary endpoint, including prior enrollment in this study.
- Participant is pregnant, nursing, or planning to become pregnant during the first 12 months after their enrollment in the study.
- Participant has presence of another anatomic or comorbid condition, or other medical, social, or psychological condition that, in the investigator's opinion, could limit the participant's ability to complete the clinical investigation or comply with follow-up requirements.
- Incapacitated individuals, defined as persons who are mentally ill, mentally handicapped, or individuals without legal authority, are excluded from the study population.

... and 36 more (see full listing online)

Locations (2 total)

Cardiovascular Institute of the South, Houma, Louisiana, United States
UT Southwestern, Dallas, Texas, United States