

Study of the R3 Vascular Drug-Eluting Bioresorbable Scaffold in Treating Below the Knee Arterial Disease

NCT04912323

Status	RECRUITING
Phase	Not Applicable
Sponsor	R3 Vascular Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (22)

- Subject is e 18 years and d 90 years of age.
 - Subject agrees not to participate in any other investigational device or drug study for a period of at least six months following the index procedure. Questionnaire-based studies, or other studies that are non-invasive and do not require investigational devices or medications are allowed.
 - Subject (or their legally authorized representative) provides written informed consent prior to any study-related procedure, using the form approved by the local Ethics Committee.
 - Subject has lifestyle limiting claudication or chronic limb threatening ischemia (Rutherford-Becker categories 3 - 5).
 - Subject agrees to complete all protocol required follow-up visits, including angiograms.
- ... and 17 more (see full listing online)

Exclusion (24)

- Pregnant or nursing subjects and those who plan pregnancy within 6 months following index procedure. (Note: Subjects of child-bearing potential must have a negative pregnancy test d 28 days prior to the index procedure and agree to use contraception for 6 months.)
 - Presence of other significant comorbid conditions, or other medical, social, or psychological conditions (such as history of substance {alcohol, cocaine, heroin, etc.} abuse), that in the investigator's opinion may limit the subject's ability to participate or comply with study instructions and follow-up (includes subjects with symptomatic COVID-19 infection in the past 2 months or asymptomatic COVID-19 positive test in the past 1 month).
 - Incapacitated individuals, defined as persons who are mentally ill, mentally handicapped, or individuals without legal authority to control their activities.
 - Life expectancy of \< 1 year.
 - Subject is non-ambulatory.
- ... and 19 more (see full listing online)

Locations (7 total)

Medical University Graz, Graz, Austria
CRCHUM Université Montreal, Montreal, Canada
Hopital Saint-Francois d'Assise, Québec, Canada
... and 4 more locations

<https://clinicaltrials.gov/study/NCT04912323>

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