

Xeltis Peripheral Artery Disease (XPAD) Bypass Conduit Early Feasibility Study

NCT06951685

Status	RECRUITING
Phase	Not Applicable
Sponsor	Xeltis
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (7)

- Subjects with femoral artery occlusion who require elective above-knee femoral popliteal bypass surgery
 - Patient has Rutherford grade 3, 4, or 5 occlusive vascular disease and TASC C or D lesions. Rutherford grade 5 may be included with a wound, ischemia and foot infection (WiFi) classification of up to grade 2, provided there are two outflow vessels with at least one reaching the pedal arch
 - At least 18 years of age at screening
 - Suitable anatomy (assessed by a pre-procedural contrasted CT scan or previous angiogram assessed up to 90 days prior to baseline)
 - Patient has been informed of the nature of the study, agrees to its provisions, and has provided written informed consent
- ... and 2 more (see full listing online)

Exclusion (20)

- Subject requires, or is scheduled for, a cardiac surgical procedure or a different vascular surgical procedure within 30 days of study procedure.
 - Presence or history of bypass in the diseased limb
 - Subject requires sequential extremity revascularizations or other procedures that require use of additional vascular grafts
 - Stroke or myocardial infarction event within 6 weeks of the procedure or evidence of prior massive stroke (Modified Rankin Scale 3 or above)
 - History of acute arterial occlusion requiring an emergent intervention
- ... and 15 more (see full listing online)

Locations (1 total)

Centro de Investigación y Manejo del Cáncer (CIMCA), San José, Costa Rica