ABSORB BTK

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25502

Source
Nationaal Trial Register

Health condition

Critical limb ischemia

Sponsors and support

Primary sponsor: Dutch Endovascular Alliance (DEAll)
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

In-stent restenosis at 12 months, defined as lumen narrowing > 50% assessed by angiography

Secondary outcome

− Technical success rate, defined as residual stenosis < 30%

− Target lesion revascularization (TLR), defined as any endovascular revascularisation of the target lesion.

− Target vessel revascularization (TVR), defined as any endovascular revascularisation of any non-target lesion in the same tibial artery as the target lesion

− Death, defined as any death during follow-up

− Minor amputation, defined as any non-limb amputation, for instance any (partial) amputation of a toe or foot.

− Major amputation, defined as any limb amputation, for instance below-, through-, or above-knee amputation

− Improvement in Rutherford-Becker classification (see appendix B for the Rutherford-Becker classification)

− Wound healing (if applicable), defined as wound closure at the time of the outpatient visit.

Study description

Background summary

N/A

Study objective

The aim of this study is to evaluate the efficacy, and feasibility of the Absorb bioresorbable scaffold in infrapopliteal hemodynamically significant arterial stenoses and occlusions.

Study design

Follow-up will be obtained at the outpatient clinic 1, 6 and 12 months after the intervention. During follow-up any complications will be registered and physical examination of the treated limb will be performed. Prior to the follow-up visit at 6 and 12 months, all patients will be analysed by treadmill test and duplex of the treated artery. At 12 months of follow-up a diagnostic catheter guided angiography will be performed.

Intervention

The Absorb everolimus-eluting bioresorbable scaffold will be used in the endovascular treatment of symptomatic tibial atherosclerotic lesions.

Contacts

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Eligibility criteria

Inclusion criteria

− Age ≥ 18 years

− At least 1 symptomatic de novo or restenotic (after only PTA) atherosclerotic tibial lesion. The lesion should be a stenosis of at least 70% or an occlusion with a maximum length of 100mm.

− At least 1 outflow artery to the foot distally to the target lesion

− Target vessel diameter ≥ 2.0 and ≤ 3.8mm (instructions for use)

− Successful crossing of the target lesion

Exclusion criteria

− PAD Rutherford-Becker classification 1-3 or 6.

− A life expectancy less than 1 year.

− Thrombus within the target lesion

− Multiple stenoses in the tibial target artery

− Acute limb ischemia

− Dissection

− Lesion length > 100mm.

− Aspirin, Clopidogrel, Heparin or Everolimus allergy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4159
NTR-old	NTR4318
Other	: none
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A