FOREST TRIAL - A randomized controlled trial comparing drug-eluting balloons and drug-eluting stents in the treatment of femoropopliteal arterial occlusive disease

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26991

Source
Nationaal Trial Register

Brief title
FOREST

Health condition

Femoro-popliteal, femoral, popliteal, drug-eluting, balloon, stent
Femoropopliteaal, femoraal, popliteaal, drug-eluting, ballon, stent

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Freedom from binary restenosis at 2 years of follow up, defined as a reduction of >50% assessed by duplex ultrasound (peak velocity ratio (PVR) >2.5)

Secondary outcome

• Technical success, defined as residual stenosis < 30% after treatment assessed on angiography during procedure.

• Procedural success, defined as procedure without complication and with technical success

• Target lesion revascularization (TLR) during follow up, defined as any repeated revascularization of the target lesion to maintain patency

• Target vessel revascularization (TVR), defined as repeat intervention of target vessel to maintain patency

• Primary patency, defined as freedom from binary restenosis and TLR during follow up

• Changes in Ankle-brachial index (ABI), assessed by treadmill test. In patients with CLI only a resting ABI will be performed

• Changes in Rutherford-Baker classification

• Improvement in disease-related health status, functioning and quality of life. As defined by a Dutch translation of the Peripheral Artery Questionnaire (PAQ).

• Major amputation rate (above the ankle)

• Mortality (all-cause mortality)

• Any other complication regarding the treatment of the femoropopliteal lesion

Study description

Background summary

Background: The optimal endovascular treatment for femoropopliteal arterial occlusive disease has yet to be assessed. Patency rates are disappointing after conventional angioplasty. Stenting techniques have improved outcomes, in particular in long and complex lesion. The presence of a stent however, also has limitations despite the improved outcomes.

Intra-arterial stenting may lead to stent thrombosis and flow pattern disruption, which may result in stent fracture or in-stent restenosis and may advocate techniques where nothing is left behind.
In the past decade drug-eluting balloons (DEB) and drug-eluting stents (DES) were introduced. Both DEB and DES have proven to posses anti restenotic features in comparison to conventional techniques.

The objective of this study is to perform a non-inferiority analysis of drug-eluting balloons with provisional stenting and primary stenting with drug-eluting stents in the treatment of femoropopliteal arterial occlusive disease. If DEB with provisional stenting turns out to be non-inferior to primary stenting with DES, than DEB may be a favourable technique, since the postoperative long-term limitations of stents will be restricted.
Methods/Design This is a prospective, randomized, controlled, single-blind, multi-center trail. The study population consists of human volunteers aged over 18, with chronic, symptomatic peripheral arterial occlusive disease (Rutherford classification 2 to 5) due to de novo stenotic or occlusive lesions of the superficial femoral artery or popliteal artery (only P1).
Subjects will either be treated with DEB and provisional stenting with a bare-metal stent, or will be primary stented with a DES. A total of 254 patients will be included (ratio 1:1).
The primary endpoint will be 2-year freedom from binary restenosis, defined as a lumen diameter reduction of <50% assessed by duplex ultrasound (peak velocity ratio <2.5).
Secondary outcomes will be technical success, target lesion revascularisation, target vessel revascularisation, changes in ankle-brachial index, changes is Rutherford classification, amputation rate and mortality rate.

Study objective

Endovascular treatment of femoropopliteal arterial occlusive disease with drug-eluting balloons with provisional stenting leads to the same angiographic and clinical outcomes as primary stenting with a drug-eluting stent

Study design

2 year

Intervention

Subjects will either be treated with a DEB and provisional stenting with a BMS, or will be primary stented with a DES.

Contacts

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Eligibility criteria

Inclusion criteria

• Age ≥ 18 years

• Patients must be willing to sign an informed consent form

• Rutherford-Baker class 2-5

• At least 1 symptomatic de novo atherosclerotic lesion in the superficial femoral artery and/or popliteal artery, section P1

• There will be no maximum lesion length

• Diameter of reference vessel between 4 to 7 mm

• The lesion should be a stenosis of at least 50% or an occlusion assessed by CT-angiography or MR-angiography or assessed by duplex ultrasound (DUS, peak systolic velocity ratio (PVR) of >2.5)

• At least 1 patent tibial runoff vessel

• Successful passage with guide wire

Exclusion criteria

• Life expectancy ≤ 1 year

• Restenotic lesions

• Acute femoro-popliteal occlusion

• Recurrent stenosis or occlusion

• Aspirin, Clopidogrel, Heparin or Paclitaxel allergy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	254
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-03-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50453
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5662
NTR-old	NTR5797
CCMO	NL57055.101.16
OMON	NL-OMON50453

Study results