Randomized comparison of FemORal drug-Eluting balloons and Stents (FOREST TRIAL) - A randomized controlled trial comparing drug-eluting balloons and drug-eluting stents in the treatment of femoropopliteal arterial occlusive disease

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON50453

Source
ToetsingOnline

Brief title
FOREST trial

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral arterial occlusive disease (PAOD)

Research involving
Human

Sponsors and support

Primary sponsor: Stichting DEAll, wetenschappelijke stichting ter bevordering van vasculair wetenschappelijk onderzoek
Source(s) of monetary or material Support: Dutch Endovascular ALLiance (DEALL)

Intervention

Keyword: Balloon, Drug-eluting, Femoropopliteal, Stent

Outcome measures

Primary outcome

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 outcome

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 description

Background summary

The optimal endovascular treatment for femoropopliteal arterial occlusive disease has yet to be assessed. The most important limitation of percutaneous treatment is patency. Bare metal stent (BMS) deployment leads to improved outcomes, in particular in long en complex lesions. Stenting however has its own limitations as it disrupts the flow pattern, which can lead to stent thrombosis or in-stent restenosis. Moreover, stents may fracture, which results in stent occlusion. In the past decade drug-eluting balloons (DEB) and drug-eluting stents (DES) were introduced. Both DEB and DES, when compared to

conventional techniques, have shown to possess anti-restenotic features.

Study objective

The objective of this study is to perform a non-inferiority analysis of drug-eluting balloons (DEB) with provisional stenting and primary stenting with drug-eluting stents (DES) 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.

Study design

Prospective, single blind, randomized, multicenter clinical trial. Subjects will be randomly assigned to treatment with either DEB or provisional stenting (spot stenting with bare-metal stents), or with primary stenting with DES. Follow-up will be obtained at 1,6,12 and 24 months after the intervention. At these moments patients will undergo physical examination and will be asked to fill in quality-of-life questionnaires. Prior to the 6, 12 and 24 months visit, patients will be analyzed by a treadmill test and duplex ultrasound of the treated artery.

Intervention

Subjects will either be treated with DEB and provisional stenting with a bare-metal stent, or will be primary stented with a DES.

Study burden and risks

Both DEB and DES are commercially available devices, which are being used as a standard of care for endovascular treatment of femoropopliteal arterial occlusive disease. Both devices perform better than uncoated devices without additional risks.
Follow up consists of 4 outpatient clinic visits, 4 questionnaires, 3 duplex ultrasounds and 3 treadmill tests. Depending on the local hospital protocol part of the outpatient clinic visits and additional tests are standard of care. Patients participating in this trial will be treated according to the best available endovascular treatment options for 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.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >= 18 years
• Patients must be willing to sign an informed consent form
• Rutherford-Baker class 2-6
• 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

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2016
Enrollment:	254
Type:	Actual

Medical products/devices used

Generic name:	Drug-eluting balloon and drug-eluting stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-05-2016

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-08-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-01-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-07-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26991
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL57055.101.16
OMON	NL-OMON26991