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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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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26991

Bron
Nationaal Trial Register

Verkorte titel
FOREST

Aandoening

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

Ondersteuning

Primaire sponsor: NA
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

2 year

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Maasstad Hospital Rotterdam Department of Vascular Surgery

Hidde Jongsma
Maasstadweg 21

Rotterdam 3079 DZ
The Netherlands
(+31) 10 2911911

Wetenschappelijk

Maasstad Hospital Rotterdam Department of Vascular Surgery

Hidde Jongsma
Maasstadweg 21

Rotterdam 3079 DZ
The Netherlands
(+31) 10 2911911

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Life expectancy ≤ 1 year

• Restenotic lesions

• Acute femoro-popliteal occlusion

• Recurrent stenosis or occlusion

• Aspirin, Clopidogrel, Heparin or Paclitaxel allergy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2016
Aantal proefpersonen:	254
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-03-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50453
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten