PTA and Drug Eluting Stents for Infrapopliteal Lesions in Critical Limb Ischemia

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ObjectiveTo investigate the performance of paclitaxel-coated balloon expandable stainless steel coronary stent for the treatment of infrapopliteal stenoses and occlusions in patients with critical limb ischemia compared to percutaneous transluminal...

Ethical review	-
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON37284

Source
ToetsingOnline

Brief title
PADI

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Critical limb ischemia, Peripheral arterial occlusive disease

Research involving
Human

Sponsors and support

Primary sponsor: Nederlandse Vereniging voor Radiologie, sectie NGIR
Source(s) of monetary or material Support: sectie NGIR van NVVR

Intervention

Keyword: drug eluting stents, interventional radiology, limb ischemia, PTA

Outcome measures

Primary outcome

The primary endpoint will be primary patency of the treated site at 6 months.

Primary patency is defined as <50% loss of luminal diameter at the treated site on CT arteriography (CTA) without re-intervention in the interim.

Secondary outcome

* Primary patency at duplex (psv ratio <2.0) of the treated sites at discharge, 3, 6 and 12 months after intervention.

* Clinical categorisation of the treated ischemic leg by means of the Rutherford classification at 3, 6 and 12 months, 2, 3, 4 and 5 years.

* Major amputation (at or above the ankle) of the trial leg at 3, 6 and 12 months, 2, 3, 4 and 5 years.

* Minor amputation (below the ankle excluding the toes) of the trial leg at 3, 6 and 12 months, 2, 3, 4 and 5 years.

* Infrapopliteal surgical bypass of the trial leg at 3, 6 and 12 months, 2, 3, 4 and 5 years.

* Infrapopliteal endovascular re-intervention of the trial leg at 3, 6 and 12 months, 2, 3, 4 and 5 years

* Patency of treated femoropopliteal sites, if applicable.

* Peri-procedural (within 30 days) complications.

* Death.

After 5 years only surveillance (medical records) of survival and amputation

will be performed until 10 years after initial treatment.

Study description

Background summary

Title
PTA and Drug Eluting Stents for Infrapopliteal Lesions in Critical Limb Ischemia
(PADI)

Study objective

Objective
To investigate the performance of paclitaxel-coated balloon expandable stainless
steel coronary stent for the treatment of infrapopliteal stenoses and occlusions in
patients with critical limb ischemia compared to percutaneous transluminal balloon
angioplasty (PTA).

Study design

Study design
Multi-center, prospective, randomised, two-arm study. Patients will be randomised on a 1:1 basis. It is anticipated that a total of 136 patients will be entered in the study. Subjects will be followed for 12 months after treatment. Study examinations will be performed at screening, during intervention, at discharge and after 3, 6 and 12 months, 2, 3, 4 and 5 years. The trial will be performed at 3 investigation centres in the Netherlands.

Intervention

Participants will be randomised to PTA or PTA plus drug eluting stent placement

Study burden and risks

Safety parameters
The safety outcome of the trial will be described in terms of the incidence of procedure or stent related serious adverse events in the 12-month period after

stent implantation. After the first 40 patients have been randomised (20 for stent placement) there will be an interim analysis for safety. This interim analysis will focus on acute thrombosis within 6 weeks after implantation. The expected percentage of thrombosis is less than 10%. If in the first 40 patients the acute thrombosis is 20% higher in either the stent group compared to the balloon angioplasty group or visa versa, which is a difference of more than 4 patients, the study will be temporarily stopped to analyse these findings. The METC will be informed and a new approval from the METC will be required to restart the study
Randomisation into the stent-group will not produce a significant burden compared to PTA alone. Procedure length will be only slightly longer in this group. Subjects in both groups will be prescribed a daily dose of 100mg acetylsalicylic acid indefinitely and a daily dose of 75mg clopidogrel for 6 months.

Burden to the patient resulting from participation in this study consists of 7 follow-up visits to the vascular surgeon and the radiology department for clinical follow-up and duplex sonography and 1 CTA examination (with injection of IV contrast medium) at 6 months. The follow-up visits are at 3, 6 and 12 months, 2, 3, 4 and 5 years after primary intervention. Data of patients undergoing major amputation of the target limb during follow-up will be passively acquired, they will not be invited for hospital visits. Of these patients only survival will be monitored.

After 5 years, all patient will passively surveilled for survival and amputation up to 10 years after initial treatment.

Contacts

Public
Nederlandse Vereniging voor Radiologie, sectie NGIR

Pettelaarpark 33, Postbus 1988
5200 BZ 's Hertogenbosch
NL
Scientific
Nederlandse Vereniging voor Radiologie, sectie NGIR

Pettelaarpark 33, Postbus 1988
5200 BZ 's Hertogenbosch
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Critical limb ischemia as a result of obstruction/occlusion of infrapopliteal (below-the-knee) arteries

Exclusion criteria

Acute limb ischemia
Absence of sufficient inflow to infrapoliteal arteries
Allergy to contrast media, heparin, acetylsalicylic acid or paclitaxel

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	136
Type:	Actual

Medical products/devices used

Generic name:	drug eluting stent
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	08-02-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT00471289

Register	ID
CCMO	NL15134.098.08