Randomized trial of Legflow® Paclitaxel eluting balloon (LPEB) with stentplacement vs. standard PTA with stentplacement for the treatment of intermediate (>5 cm and < 15 cm) and long (>15 cm) lesions of the superficial femoral artery (SFA). The RAPID trial.

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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-OMON40039

Source
ToetsingOnline

Brief title
The RAPID trial

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis of the superficial femoral artery

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Cardionovum Sp.z.o.o, Warsaw, Poland,Cardionovum Sp.z.o.o.;Warsaw;Poland

Intervention

Keyword: Drug eluting balloon, Peripheral arterial disease, Stent, Superficial femoral artery

Outcome measures

Primary outcome

The primary endpoint is absence of binary restenosis rate.

Main study parameters are age, gender, relevant co-morbidity, and several

disease and procedure related parameters.

Secondary outcome

Secondary endpoints are reoclusion rate, target-lesion revascularization rate,

clinical success, hemodynamic success, major amputation rate, complication

rate, mortality rate and cost-effectiveness. ,

Study description

Background summary

Atherosclerotic lesions in the superficial femoral artery may cause intermittent claudication and critical limb ischemia, leading to serious complications such as tissue loss, amputation and even death. Revascularization relieves symptoms and might prevent these complications. Over the last decade, endovascular repair has become the preferred treatment for femoral arterial obstructive disease. No definitive consensus has emerged concerning the best endovascular strategy, for example if balloon angioplasty or stenting is superior. However, literature is most supportive of balloon angioplasty with stenting in longer segment lesions in the SFA. Paclitaxel covered balloons have

been found to reduce neo-intimal hyperplasia, and reduce restenosis. Recently, the Legflow® Paclitaxel eluting balloon (Cardionovum Sp.z.o.o., Warsaw, Poland) has been introduced. This Paclitaxel eluting balloon is covered with Shellac, to obtain an equally distributed tissue concentration of Paclitaxel, reaching an optimal dosis at a short inflation time of 45 seconds because of a high delivery dose. This results in reduced neo-intimal growth, and reduces the risk of local and systemic complications. In porcine models Paclitaxel/Shellac coated balloons show a higher tissue concentration over time than other Paclitaxel balloons, requiring a shorter inflation time for optimal tissue concentrations. However, no randomized controlled trials have been performed on this specific balloon in the superficial femoral artery. We hypothesize that the Legflow PEB balloon in combination with Nitinol stents will lead to significantly less hemodynamically significant restenosis when compared to conventional uncovered balloons combined with Nitinol stents in treatment of intermediate (>5 cm and < 15 cm) and long (> 15 cm) SFA lesions.
Hypothesis: The use of PDEB will reduce the restenosis rate of treated SFA lesions compared to conventional PTA with stent.

Study objective

The primary objective is to assess the difference in absence of binary restenosis rate of endovascular treatment of intermediate and long lesions of the superficial femoral artery with the Legflow® PEB and nitinol stent, when compared to uncoated conventional balloon angioplasty and nitinol stent after a 2-year follow-up.
The secondary objectives are to asses the reocclusion rate, target-lesion revascularization rate, clinical success, hemodynamic success, major amputation rate, complication rate, mortality rate and cost-effectiveness of endovascular treatment of intermediate and long lesions of the superficial femoral artery with the Legflow® PEB and nitinol stents, when compared to conventional balloon angioplasty and nitinol stent.

Study design

A randomized, controlled, patient-blind, multi-center trial.

Intervention

The intervention group will undergo endovascular dilatation of intermediate and long lesions of the SFA with the LegFlow® Paclitaxel eluting balloon followed by placement of a nitinol selfexpandable stent (Supera®, IDEV inc., Webster TX). The control group will undergo endovascular dilatation of the SFA with standard PTA followed by placement of the same Supera® stent.

Study burden and risks

All devices, guidewires and catheters have CE-approval. Participating patients will need to make five study-related hospital visits, which is standard for this type of treatment. Five non-invasive duplex-ultrasound (DUS) studies and five non-invasive ABI measurements with treadmill test will be performed, as well as non-invasive toe pressure measurements (TcpO2). When compared to the standard pre-procedural imaging and follow-up imaging, patients do not need to make extra hospital visits. When treadmill test and DUS show possible asymptomatic significant restenosis >75%, or symptomatic restenosis >50% patients will receive additional digital subtraction angiography and (re)intervention. This is routine in daily vascular practice. Furthermore, patients will be asked to fill out a 13-item questionnaire at every follow-up moment. The Shellac used on the catheter is recognized as safe by the FDA (E904). Recently, the use of the DIOR 2 balloon (also covered with Shellac and used in the cardiac field) for in-stent stenosis, and restenosis of small cardiac vessels was safe at one year. TLR of the treated stenoses in this study was 12%.

Contacts

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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 over 18
- Symptomatic, atherosclerotic intermediate (>5 cm and < 15 cm) and long (>15 cm) lesions of the superficial femoral artery.
- Rutherford class 2-6
- At least one patent below-the-knee artery with uninterrupted flow to the pedal arch.
- Signed informed consent
- Randomization will be performed after advancement of a guide wire across the target SFA lesion with use of an automated web-based randomization tool.

Exclusion criteria

- Life expectancy less than one year.
- Previous endovascular or surgical treatment of the target superficial femoral artery
- Inability to comply with the follow-up schedule.
- Mental disability that hinders the ability to understand and comply with the informed consent.
- Pregnancy or breast-feeding.
- Severe renal failure (e-GFR <30 mL/min/1.73 m2).
- Known allergy to iodinated contrast agents.
- Contra-indication for anti-coagulation (Aspirin as well as Clopidogrel).
- (Acute) limb ischemia caused by SFA or popliteal artery aneurysmal disease
- Obstruction caused by SFA or popliteal artery dissections

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2012
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	27-04-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-07-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-09-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	20-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-05-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL39391.100.12