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Legflow® Paclitaxel Eluting Balloon (LPEB) with stentplacement versus standard percutaneous transluminal angioplasty with stentplacement for the treatment of occlusive disease of the superficial femoral artery

Submission date
13/06/2012

Recruitment status
No longer recruiting

Registration date
30/07/2012

Overall study status
Completed

Last Edited
25/02/2021

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Atherosclerosis is a condition where the blood vessels (arteries) become narrow. Atherosclerosis affecting the superficial femoral artery (a large artery in the thigh) may cause pain and reduced blood flow to the leg, leading to serious complications such as tissue loss, amputation and even death. Surgery can be used to restore the blood flow, relieve symptoms and prevent or delay these complications. Percutaneous transluminal angioplasty (PTA) is a procedure to open up the blocked artery using a small plastic tube (catheter) with a balloon and a small mesh tube (stent) at the end. When the tube is in place, it inflates to open the artery. The stent expands so that it acts as a scaffold and holds open the artery. However, the artery becomes narrow again (restenosis) in 45% of patients at 2 years follow-up. Using balloons covered in paclitaxel/shellac may prevent the artery walls from thickening. The aim of this study is to demonstrate whether there is a beneficial effect of using paclitaxel/shellac covered balloons over standard PTA on the occurrence of restenosis.

Who can participate?
Patients over 18 years old with atherosclerosis of the superficial femoral artery

What does the study involve?
Participants are randomly allocated to one of two groups. The intervention group undergo PTA using the paclitaxel/shellac covered balloons followed by placement of a stent. The control group undergo standard PTA followed by placement of a stent. Restenosis rates are compared at 1, 6, 12 and 24 months follow-up and during unplanned visits.

What are the possible benefits and risks of participating?
A possible benefit is reduction of restenosis. The risks are the same as standard PTA and stenting. The use of similar balloons is safe in coronary (heart) artery interventions.

Where is the study run from?
St Antonius Hospital Nieuwegein (Netherlands)

When is the study starting and how long is it expected to run for?
June 2012 to January 2014

Who is funding the study?
St Antonius Hospital Nieuwegein (Netherlands)

Who is the main contact?
Dr Jean-Paul P M de Vries
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL39391.100.12

Study information

Scientific Title
RAndomized trial of Legflow® PaclItaxel Eluting Balloon (LPEB) with stentplacement vs. stanDard percutaneous transluminal angioplasty (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

Acronym

RAPID

Study objectives
Treatment with the Legflow® Paclitaxel eluting balloon in combination with Nitinol stents will lead to significantly lower restenosis rates when compared to conventional uncoated balloon angioplasty combined with the same Nitinol stents in treatment of intermediate (>5 cm and < 15 cm) and long-segment (> 15 cm) SFA lesions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the St. Antonius Hospital Nieuwegein, 27/04/2012, ref: R-12.009

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Atherosclerotic lesions of the superficial femoral artery

Interventions
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.

Intervention Type
Procedure/Surgery

Primary outcome measure
Absence of binary restenosis, measured with duplex ultrasound (DUS), and if indicated with digital subtraction angiography (DSA), at 1, 6, 12 and 24 months follow-up and unplanned visits

Secondary outcome measures
1. Immediate outcome: Ankle Brachial Index (ABI), toe pressures, angiography
2. Clinical outcome: periferal artery questionnaire
3. Hemodynamic outcome: ankle-brachial index (ABI), Toe pressures
4. Reocclusion rate: DUS, DSA
5. Target-lesion revascularization: Follow-up
6. Target-extremity revascularization: Follow-up
7. Mortality rate: Follow-up
8. Amputation rate : Follow-up
9. Rate of device-specific problems: Follow-up with DUS, DSA when indicated

All endpoints will be scored at regular follow-up and during unplanned visits.

Overall study start date
01/06/2012

Completion date
01/01/2014

Eligibility

Key inclusion criteria
1. Age over 18
2. Symptomatic, atherosclerotic intermediate (>5 cm and < 15 cm) and long (>15 cm) lesions of the superficial femoral artery.
3. Rutherford class 2-6
4. At least one patent below-the-knee artery with uninterrupted flow to the pedal arch
5. Signed informed consent
6. Randomization will be performed after advancement of a guide wire across the target SFA lesion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
176

Total final enrolment
160

Key exclusion criteria

1. Life expectancy less than one year
2. Previous endovascular or surgical treatment of the target superficial femoral artery
3. Inability to comply with the follow-up schedule.
4. Mental disability that hinders the ability to understand and comply with the informed consent
5. Pregnancy or breast-feeding
6. Severe renal failure [estimated glomerular filtration rate (e-GFR) <30 mL/min/1.73 m^2]
7. Known allergy to iodinated contrast agents
8. Contra-indication for anti-coagulation (aspirin as well as clopidogrel)
9. (Acute) limb ischemia caused by SFA or popliteal artery aneurysmal disease
10. Obstruction caused by SFA or popliteal artery dissections

Date of first enrolment
01/06/2012

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
PO Box 2500
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Sponsor information

Organisation
St Antonius Hospital Nieuwegein (Netherlands)

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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/01jvpb595

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Antonius Ziekenhuis

Alternative Name(s)
St. Antonius Hospital, Sint Antonius Ziekenhuis

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/03/2013		Yes	No
Results article	results	01/12/2017	25/02/2021	Yes	No