

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	☐ Prospectively registered ☒ Protocol
Registration date 30/07/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/02/2021	Condition category Circulatory System	☐ 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Multicentre randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Immediate outcome: Ankle Brachial Index (ABI), toe pressures, angiography
2. Clinical outcome: peripheral 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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Nieuwegein

Netherlands

3435 CM

Sponsor information

Organisation

St Antonius Hospital Nieuwegein (Netherlands)

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

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?
Results article	results	01/12/2017	25/02/2021	Yes	No
Protocol article	protocol	28/03/2013		Yes	No