Comparison of Supera and Absolute Pro stent systems for femoro-popliteal lesions; a feasibility study

Published: 05-11-2015
Last updated: 19-04-2024

Both the Supera and the Absolute Pro Stent System are self-expandable stents that are frequently used in regular clinic practice in patients with obstructive vascular disease. Results of both stent systems have been evaluated in several studies and...

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

Summary

ID

NL-OMON42369

Source
ToetsingOnline

Brief title
SAP feasability study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
intermittent claudication, peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: femoro-popliteal, peripheral arterial disease, stenting

Outcome measures

Primary outcome

- Absence of binary restenosis (* 50% re-obstruction) of the target lesion as assessed by duplex ultrasound after 12 months without interval clinically driven reintervention

- Number of clinically driven target lesion revascularisation within 12 months

Secondary outcome

- Changes in pain-free walking distance and absolute walking distance as assessed by standardized exercise test

- Changes in quality of life as assessed by EuroQol 5 Demension (EQ-5D) questionnaire

- Clinical complications (number of adverse events, serious adverse events and major adverse events)

- Sustained clinical improvement as assessed by distribution of Rutherford stages

- Procedural success (technical success, device success and procedural complications)

Study description

Background summary

Previous studies on stenting of femoro-popliteal arteries are often representing the results of a single device. Not many studies are comparing the

performance of different stent types in a prospectively randomised setting. Two flexible stent types with good performance and high patency rates in the femoro-popliteal artery are the Supera and the Absolute Pro Stent Systems (both from Abbott Vascular) with 1 year primary patency rates of 78% and 83.3-85.8% respectively.

Study objective

Both the Supera and the Absolute Pro Stent System are self-expandable stents that are frequently used in regular clinic practice in patients with obstructive vascular disease. Results of both stent systems have been evaluated in several studies and the results have been published.
Although both stent systems show a good performance, head-to-head comparison of both stent systems is not well possible, due to different study designs, different outcome measurements and differences in in- and exclusion criteria. Head-to-head comparison of 2 stent systems is not (yet) very common in the field of Vascular Surgery, but very common in Cardiology to assess superiority of either one of the systems.
The aim of this study is to compare the performance and clinical outcome of the Absolute Pro and the Supera Stent System in symptomatic PAD patients (Rutherford 2-4) with femoro-popliteal lesions.

Study design

A single centre randomised controlled feasibility study

Intervention

Randomisation between Supera and Absolute Pro stenting

Study burden and risks

For this study the risks for PTA with stenting are applicabale. Though, patients that will be asked for this study will receive PTA with stenting anyway, even if they do not want to participate in this study. The burden includes completing a questionnaire (3 times) and whether or not additional to a maximum of 2 times 2 non-invasive tests to determine the stent and artery patency.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- PAD (ABI <0.90 and/or a decline of >0.15 after exercise test), Rutherford category 2, 3 or 4
- Significant stenoses (* 50%) and/or occlusions in the superficial femoral artery and/or popliteal artery (P1)
- Eligible for endovascular treatment according to international guidelines (with the expectation of stenting after PTA)
- Adequate inflow (<50% stenosis) either pre-existing or successfully re-established prior to target lesion treatment without complications (e.g. embolization, thrombotic event, perforation, etc.)
- Age * 18

Exclusion criteria

- Patients with PAD Rutherford category 5 and 6
- Contralateral lesions that require treatment within 30 days before or after the procedure
- Contra-indication for anticoagulant therapy
- Life expectancy < 1 year
- Known contrast allergy

- Pregnancy
- Unable to complete a questionnaire in the home language

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Supera and Absolute Pro stent systems
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-11-2015
Application type:	First submission
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	NL53101.100.15