Heparin-bonded endoluminal bypass versus surgical femoro-popliteal bypass; a randomized controlled trail

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To demonstrate the equality of a heparin bonded ePTFE covered stent-graft with the femoropopliteal bypass for long lesions in the superficial femoral artery

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

Summary

ID

NL-OMON32859

Source
ToetsingOnline

Brief title
Surgical versus percutaneous bypass trail / SUPERB-trail

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriosclerosis, vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Alysis Zorggroep
Source(s) of monetary or material Support: Elisabeth Stichting

Intervention

Keyword: bypass, endoluminal, femoropopliteal occlusion, heparin-bonded

Outcome measures

Primary outcome

Primary endpoints:

Primary, primary-assisted and secondary patency

Secondary outcome

Secundaire endpoints:

Complications

Clinical improvement

Surgical and endovascular re-interventions

Quality of Life

target lesion revascularization

Subgroup analysis:

-patients with disabling claudication (Rutherford 3) will be analyzed

separately using pain-free and maximal walking distance as additional endpoint

- patients with ischemic restpain and necrosis (Rutherford 4-6) will be

analyzed using limb salvage and major amputation as endpoints

Study description

Background summary

The treatment of first choice of long superficial femoral artery obstructions still consists of surgical venous femororpopliteal bypass. The one year patency

of this procedure is 87% and the four year patency 70%.
In recent years endovascular techniques have advanced and provided new treatment options for peripheral vascular disease. Results of an angioplasty of the SFA seem to depend on the length of the lesion. For short lesions the results are good with an one year patency of 80%. But for longer lesions the one year patency of nitinol stents is only 63%.
One of the major limiting issues appears to be in-stent re-stenosis. With the development of ePTFE covered stents the patency has improved to 83% in one year and 63% in two years (comparable to the prosthetic bypass. Heparin bonded stents have improved the results to a two year patency of 69-81%.
Recently the heparin bonded stent has been integrated with the ePTFE covered stent. Using this technique the results may improve to the level of the current gold standard, the venous femoropopliteal bypass. Advantages of the endoluminal techniques would be related to the minimal invasieve character: less pain, earlier recovery and less early complications.

Study objective

To demonstrate the equality of a heparin bonded ePTFE covered stent-graft with the femoropopliteal bypass for long lesions in the superficial femoral artery

Study design

Prospective randomised controlled trail

Intervention

Patients are randomised between surgical venous femoropopliteal bypass and endoluminal stent-graft

Study burden and risks

Patients who would receive an endoluminal bypass, but in who the procedure fails, will receive a surgical bypass during the same session.

The first three months (one, three and six months postoperatively) patients will have to complete a questionnaire before their OPD visit.

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

patients over 18 years of age
informed consent
>10 cm stenosis or occlusion of the SFA or popliteal artery, nort extending below knee level
rutherford category 3-6
indication for surgical bypass
distal runoff of one or more vessels
resting ABI <0,8 in the study limb prior to procedure
de novo stenosis or restenosis (>50%) of occlusion of the native SFA
orifice and proximal 1 cm of SFA are patent
popliteal artery is patent at P2 segment to the trifurcation
diameter of native SFA and popliteal artery are 4.3-7.5 mm

Exclusion criteria

patient unsuitable for administration of contrast agent (previous lifethreathening reaction)
pregnancy
dementia or altered mental status that would prohibit giving conscious informed consent
need for major surgical or vascular procedures within one month

untreated flowlimiting aortoiliac occlusive disease
any previous stenting or surgery in the target vessel
severe ipsilateral common femoral/profunda disease requiring surgical intervention
perioperative unsuccesful ipsilateral percutaneous vascular procedure to treat inflow disease prior to enrollment
femoral or popliteal aneurysm of target vessel
non-artherosclerotic disease resulting in occlusion (eg embolism, Buerger's disease, vasculitis)
prior ipsilateral femoral artery bypass
severe medical comorbidities or other medical condition that would preclude compliance with study protocol
serum creatinine >2,5 mg/dL within 45 days prior to study procedure unless subject is currently on dialysis
major distal amputation (above the transmetatarsal) in ther study or non-study limb
septicemia or bacteremia
any previously known coagulation disorder
contraindication to anticoagulation or antiplatelet therapy
Known allergies to stent/stentgraft components
patients with known hypersensitivity to heparin including those who have had a previous incidence of heparin induced thrombocytopenia type II
planned surgical procedure or amputation after enrollment of the patient

Study design

Design

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):	15-10-2010
Enrollment:	222
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL29652.091.09

Study results

Date completed:	01-07-2020
Results posted:	11-11-2020
Actual enrolment:	129

First publication
22-10-2020