ISRCTN18315574 https://doi.org/10.1186/ISRCTN18315574

Minimal invasive balloon expansion versus bypass operation to treat complicated occlusions and stenoses of the femoral and popliteal arteries

Submission date
25/01/2016

Recruitment status
No longer recruiting

Registration date
29/04/2016

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Atherosclerosis is a serious disease where a fatty substance, called plaque, builds up in the arteries. Over time, plaque causes hardening and narrowing of the arteries, which leads to reduced flow of blood through the blood vessels. Over time this can cause the main arteries in the legs, usually the femoral (thigh level) and/or popliteal (knee level) arteries, to become narrowed (stenosed) or blocked (occluded). This can cause a severe cramping pain in the legs when exercising, as the restricted blood flow cannot deliver enough oxygen to the leg muscles. As the arteries become narrower, patients begin the feel pain even when at rest and are at severe risk of developing ulcers or gangrene (critical limb ischaemia). At this point, the only viable treatment option is to surgically restore blood flow to the leg (revascularisation). This is done by either bypass surgery (where a superficial (close to the skin surface) vein is used to divert blood around the obstruction) or endovascular techniques (where the blocked artery is reopened using a balloon (angioplasty) and possibly held open with a mesh tube (stent) which is placed inside the artery). The current international guidelines (TransAtlantic Inter-Society Consensus, TASC II) recommend that short blockages (TASC II Type A and B) be treated using endovascular techniques and long blockages (TASC II Type C and D) of the femoral and/or popliteal arteries be treated using bypass surgery. Most patients prefer to have endovascular surgery as it is much less invasive however it is not known whether these techniques would be as effective as bypass surgery in long blockages. The aim of this study is to compare the effectiveness and complication rates of endovascular and bypass surgery in long blockages of the femoral and/or popliteal arteries.

Who can participate?
Patients aged 30 years or over who have blocked arteries in their lower legs which is causing them disabling claudication or critical limb ischaemia.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive

the standard bypass surgery. This involves the removal of the greater saphenous vein (superficial vein running from the foot to the upper thigh) from the affected leg, and attaching (grafting) it above and below the blockage so that the blood can go around it. Participants in the second group receive endovascular surgery. This involves a tube being placed inside the affected artery with a small balloon on the end. This balloon is then inflated to flatten the blockage up against the artery wall. A small mesh tube is then placed in the artery to keep it open. After the procedures, participants in both groups have an angiography (type of x-ray to see inside the blood vessels) in order to judge the success of the operation. Participants in both groups also have an ultrasound scan of their arteries at the start of the study, after 2 and 4 weeks and after 3, 6 and 12 months in order to monitor the patency (openness) of the arteries to make sure they are not becoming narrowed again (restenosis).

What are the possible benefits and risks of participating?
There are no specific benefits of taking part, as participants who receive surgery anyway. There are no specific risks of taking part other than the general risks associated with undergoing major surgery.

Where is the study run from?
Paracelsus Medical University Salzburg (Austria)

When is the study starting and how long is it expected to run for?
March 2016 to March 2021

Who is funding the study?
Paracelsus Medical University (Austria)

Who is the main contact?
Dr Klaus Linni
k.linni@salk.at

Contact information

Type(s)
Public

Contact name
Dr Klaus Linni

Contact details
Paracelsus Medical University
Müllner Hauptstraße 48
Salzburg
Austria
5020
+43 662 4482 53201
k.linni@salk.at

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Stent versus bypass for femoropopliteal TASC II Type C and D lesions: a prospective randomised trial

Study objectives
Null hypothesis:
There will be no difference between percutaneous transluminal angioplasty (PTA) with stent and bypass operation regarding patency in patients undergoing revascularization of the lower limb due to TASC II Type C or D femoropopliteal lesions.

Experimental Hypothesis:
There is a difference between both therapies concerning patency rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local research ethics committee, Salzburg (Austria), 30/09/2015, ref: 415-E/1938/3-2015

Study design
Prospective randomised parallel 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 below to request a patient information sheet.

Health condition(s) or problem(s) studied
Atherosclerosis

Interventions

Patients are allocated to one of two groups by computer generated randomizing. Block variables are TASC C lesions, TASC D lesions, Fontaine Stage IIb (intermittent claudication) and Fontaine Stage III+IV (critical limb ischemia).

Group 1: Participants receive a bypass operation with ipsilateral greater saphenous vein. The procedure is carried out in general anesthesia oder regional anesthesia. First arteries for proximal and distal anastomosis are exposed. Then the preoperatively marked ipsilateral greater saphenous vein is harvested via multiple vertical skin incisions with intervening cutaneous bridges. The vein is prepared for the bypass with ligation of side branches and lysis of vein valves with a valvulotome (a small hook). Before clamping of the arteries 70-100 IE/kg heparin are administered intravenously, followed by clamping and incision of the artery. The next step is the proximal anastomosis between artery and vein bypass. Thereafter the bypass is placed subcutaneously for the distal anastomosis. Afterwards the arterial clamps are removed to ensure bloodstrem to the distal artery and control the leakproofness of the anastomoses. At the end of the procedure a control angiography, bleeding control and wound closure are carried out. The procedure takes approximately three hours. After five to seven days the patient can leave the hospital.

Group 2: Participants receive a percutaneous transluminal angioplasty with stent placement. The procedure is carried out in local anesthesia in the operating room using a c-arm. After puncture of the ipsilateral or contralateral common femoral artery the guide wire and introducer sheath are inserted under fluoroscopy. Thereafter 5000 IE heparin are administered. In case of successfull passing of guidewire and catheter of the complicated femoropopliteal lesions predilatation takes place by balloon catheter followed by self expandable stent placement and post dilatation. Technical success is achived in case of reststenosis of less than 30 percent in completion angiography. After removing of the sheath the common femoral artery is sealed with a closure device. The procedure takes approximately one and a half hours. If the next 24 hours are uneventful, the patient can leave the hospital.

Post-operatively the patients receive aspirin 100 mg per day (Group 1) or aspirin 100 mg per day plus Clopidogrel 75 mg per day for six weeks (Group 2). During hospital stay the patients get low-molecular-weight heparin subcutaneously. The follow up in the outpatient clinic is performed after two and four weeks, 3, 6 and 12 months.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Technical success is measured using control angiography at the end of the procedure
2. Primary and secondary patency is measured using clinical examination and ultrasound examination at baseline, 2 weeks, 4 weeks, 3 months, 6 months and 12 months

Secondary outcome measures

1. Local complications (e.g. surgical site infection, bleeding) are measured using clinical and ultrasound examination at baseline, 2 weeks, 4 weeks, 3 months, 6 months and 12 months. If extensive local complications computed tomography angiography is performed. For surgical site infections blood samples and samples for bacterial culture are taken.
2. Systemic complications (e.g. myocardial infarction, stroke) are measured using clinical examinations at baseline, 2 weeks, 4 weeks, 3 months, 6 months and 12 months
3. Limb salvage rate is determined using Kaplan Meier estimation at the end of the study

4. Survival rate is determined using Kaplan Meier estimation at the end of the study
5. Costs are calculated by the hospital's accounting department at the end of the study

Overall study start date
01/03/2016

Completion date
01/03/2021

Eligibility

Key inclusion criteria
1. Aged 30 years and over
2. Peripheral arterial occlusive disease of the lower extremity due to atherosclerosis
3. Disabling claudication (walking distance < 200 m) or critical ischemia (rest pain and/or tissue loss)
4. Radiologically verified long lesions (TASC II Type C or D) of the femoral and/or politeal artery
5. Symptoms for more than 2 months
6. Unimpaired ipsilateral iliac arteries
7. Capacity to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
218

Total final enrolment
218

Key exclusion criteria
1. Acute ischemia
2. Embolic occlusion of the femoropopliteal segment
3. Trauma
4. Non-disabling claudication (walking distance > 200 m)
5. Radiologically verified short femoropopliteal lesions (TASC II Type A and B)
6. Vasculitis
7. Renal insufficiency (glomerular filtration rate < 45 ml/min/1.73 m2)
8. No informed consent
9. Pregnancy
10. Patient too frail for bypass surgery: American Society of Anesthesiologists (ASA) - Class >3

Date of first enrolment
08/03/2016

Date of final enrolment
20/07/2020

Locations

Countries of recruitment
Austria

Study participating centre
Paracelsus Medical University Salzburg
Müllner Hauptstrasse 48
Salzburg
Austria
5020

Sponsor information

Organisation
Paracelsus Medical University (PMU)

Sponsor details
Department of Department of Vascular and Endovascular Surgery
Müllner Hauptstraße 48
Salzburg
Austria
5020

Sponsor type
University/education

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type
University/education

Funder Name
Paracelsus Medical University

Results and Publications

Publication and dissemination plan
Planned publication of study results in a peer-reviewed journal, with interim analysis after 3 years and end results after 5 years.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Florian Enzmann MD, PhD (fkenzmann@gmail.com). The researchers are able to provide anonymized patient level data and have done so for two other research projects (a meta-analysis and a retrospective data analysis) upon direct personal request after review of the project details.
Type of data: Excel files – with clinical and technical data (anonymized).
Data will become available after publication of the end results, depending on the review process – probably September 2021. The researchers will provide data upon direct personal request for the next 10 years – only for research projects.
Access criteria – research projects (meta-analyses, cost-effectiveness calculations etc). Data will only be shared with other medical professionals/researchers for specific research projects after review of their research proposal.
Patient consent included anonymous sharing and publication of patient-level data. Data anonymisation was performed with a number and letter code specific for each patient. The researchers agreed not to provide data for any commercial use.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	2-year results	23/12/2019	12/08/2022	Yes	No
Results article	4-year results	17/02/2022	12/08/2022	Yes	No
Results article	Long-Term Outcome of Bypass Surgery versus Endovascular Revascularization in Long Femoropopliteal Lesions	17/05/2023	10/05/2024	Yes	No
Results article	Long-Term Results of Endovascular Treatment with Nitinol Stents for Femoropopliteal TASC II C and D Lesions	05/09/2022	10/05/2024	Yes	No
Results article	Secondary analysis	09/09/2024	12/09/2024	Yes	No