

Angioplasty or bypass surgery in intermittent claudication

Submission date 09/05/2008	Recruitment status Stopped	☒ Prospectively registered ☒ Protocol
Registration date 13/11/2008	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 12/06/2017	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The build-up of fatty deposits (atherosclerotic lesions) on the walls of the superficial femoral artery, the main artery of the leg, may cause intermittent claudication, a painful ache in the legs when walking. In addition to medical treatment and walking exercise, restoration of the blood circulation (revascularization) is necessary in many patients. There are two main types of revascularisation. Angioplasty involves widening the artery by inflating a tiny balloon inside the vessel, and placing a short wire-mesh tube (stent) to allow the blood to flow more freely. Artery bypass graft involves taking a blood vessel from another part of the body and using it to bypass the blockage. The best method for lesions with a length of more than 10 cm and the possibility for an above-the-knee bypass is uncertain and is widely based on personal preference and institution policy rather than on evidence from studies. The aim of this study is to compare stent-protected balloon angioplasty with above-the-knee bypass surgery in patients with intermittent claudication.

Who can participate?

Patients with intermittent claudication caused by complex superficial femoral artery lesions with a length of more than 10 cm and the possibility for an above-knee bypass anastomosis.

What does the study involve?

Participants are randomly allocated to undergo either stent-protected balloon angioplasty or above-the-knee bypass surgery. All participants are followed up for 24 months to compare the proportion of surviving patients who show an improvement without the need for repeated revascularization or amputation.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Technische Universitaet Munchen (Germany)

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

July 2009 to April 2014

Who is funding the study?

1. German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany)
2. Study Centre of the German Surgical Society (SDGC) (Germany)

Who is the main contact?

Prof. Hans-Henning Eckstein

Contact information

Type(s)

Scientific

Contact name

Prof Hans-Henning Eckstein

Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT01177033

Protocol serial number

DRG. No. 222

Study information

Scientific Title

Angioplasty or Bypass surgery in intermittent Claudication (ABC): a randomised controlled trial for patients with complex lesions of the superficial femoral artery

Acronym

ABC

Study objectives

The objective of this study is to evaluate the safety and efficacy of two therapeutic strategies (operative versus endovascular) in the treatment of patients with complex atherosclerotic lesions of the superficial femoral artery (SFA).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval pending from the Primary Ethics Committee in Munich as of 09/05/2008. The study should be approved after the funding by DFG is guaranteed.

Primary study design

Interventional

Study design

Phase III randomised multicentre two-armed parallel-group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Peripheral arterial occlusive disease (PAOD)

Interventions

Intervention type I: Best endovascular treatment (stent-protected angioplasty)

Intervention type II: Best surgical treatment (femoro-popliteal bypass above the knee with autologous vein (1° choice) or a prosthetic graft (if vein is not available))

Duration of intervention per patient: Dependant on the method of treatment

Follow-up per patient: 24 months

Intervention Type

Procedure/Surgery

Primary outcome(s)

Clinical improvement of greater than one class without the need for repeated target lesion revascularisation (TLR) within 24 months in surviving patients as assessed by treadmill testing (3.2 km/h, 12% incline).

Key secondary outcome(s)

Clinical endpoints:

1. Periprocedural complications, in-hospital mortality, mortality and amputation rates within 24 months
2. Initial and absolute claudication distance after 12 and 24 months

Procedural and morphological endpoints:

3. Greater than 50% restenosis of the target lesion or greater than 50% bypass stenosis
4. Repeated target lesion revascularisation (TLR) and repeated target extremity revascularisation (TER) within 24 months

Haemodynamic endpoints:

5. Immediate and sustained ankle brachial index (ABI) improvement of greater than 0.15 during follow-up

Further secondary endpoints:

6. Quality of life, assessed using 86-item disease-specific questionnaire (PAVK 86), 36-item Medical Outcome Study Short-Form Health Survey (MOS-SF 36)
7. Total costs of treatment modalities

Completion date

01/04/2014

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Intermittent claudication (IC) class 2 or 3 (Rutherford classification) as assessed by treadmill testing (3.2 km/h, 12% incline) lasting greater than three months caused by multiple stenoses or an occlusion of the SFA with a target lesion length of 10 - 20 cm
2. Failed conservative therapy and the desire of the patient for further treatment because he or she is either unable to perform normal work or has serious impairment of other important activities
3. Ankle brachial pressure index greater than 0.3

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Greater than 50% stenosis or occlusion of the common and/or the deep femoral artery and the popliteal artery
2. Unsuitability of treadmill testing
3. Severe co-morbidities with a life expectancy of less than two years
4. Contraindications for antiplatelet agents and/or anticoagulants
5. Surgical or endovascular intervention on the index leg within the last six months

Date of first enrolment

01/07/2009

Date of final enrolment

01/04/2014

Locations

Countries of recruitment

Austria

Germany

Study participating centre
Technische Universitaet Munchen
Munich
Germany
81675

Sponsor information

Organisation
Munich Technical University (Technische Universitaet Munchen) (Germany)

ROR
<https://ror.org/02kkvpp62>

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Study Centre of the German Surgical Society (SDGC) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/07/2011		Yes	No