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Angioplasty or bypass surgery in intermittent claudication

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01177033

Secondary identifying numbers
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.

Study design
Phase III randomised multicentre two-armed parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
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 measure
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).

Secondary outcome measures
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

Overall study start date
01/07/2009

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

Age group
Adult

Sex
Both

Target number of participants
470

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)

Sponsor details
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Dean of the Medical Faculty
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Germany
81675

Sponsor type
University/education

Website
http://portal.mytum.de/navigation_view

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/07/2011		Yes	No