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Angioplasty or bypass surgery in critical limb ischemia

Submission date 25/05/2011	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/01/2012	**Overall study status** Stopped	
Last Edited 31/01/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG No. 247

Study information

Scientific Title
Angioplasty or bypass surgery in critical limb ischemia: a randomised controlled trial for patients with ischemic rest pain or tissue loss of the legs

Study objectives
Endovascular treatment is not inferior as compared to operative treatment in patients with ischemic rest pain or tissue loss of the legs (consistent to Fontaine stages III or IV and Rutherford classes 4 to 6)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Open multi-centre randomised two-armed parallel group study

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
Critical limb ischemia

Interventions
As of 31/01/2012, this study was stopped due to patient recruitment issues.

Intervention type I: Best endovascular treatment (angioplasty +/- stent)
Intervention type II: Best surgical treatment (below the knee vein bypass)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Perioperative death (POD, 30 days)
2. Any major adverse limb event (MALE) within 1 year
2.1. Above ankle amputation of the index limb
2.2. Major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy /thrombolysis)

Secondary outcome measures
1. Clinical safety endpoints
1.1. Major adverse cardiovascular event (MACE): myocardial infarction, stroke or death (any cause) within 30 days
1.2. Any MALE (definition see above) within 30 days
1.3. Above-ankle amputation within 30 days
2. Clinical efficacy endpoints
2.1. Any MALE (definition see above) within 2 years
2.2. Primary sustained clinical improvement: upward shift on the Rutherford or Fontaine classifcation to a level of intermittent claudication (IC) without the need for repeated target lesion revascularization (TLR) in surviving patients and without the need for unplanned amputation within 2 years
2.3. Secondary sustained clinical improvement: upward shift on the Rutherford or Fontaine classification to a level of IC including the need for repeated TLR in surviving patients and without the need for unplanned amputation within 2 years
2.4. Above ankle amputation of the index limb within 2 years
2.5. Amputation-Free Survival (AFS): above ankle amputation of the index limb or death (any cause) within 2 years
2.6. Any reintervention or above ankle amputation of the index limb within 2 years
2.7. Death (any cause) within 2 years
3. Haemodynamic endpoints (30 days, 3, 6, 12, 18, 24 months)
3.1. Failure to increase Ankle brachial Index (ABI) by at least 0.15 post-procedure as compared to baseline value
3.2. Decrease in ABI by 0.15 or greater as compared to post-procedure value
3.3. Duplex ultrasound or angiography demonstrating occlusion of graft or any treated vessel, or >50% stenosis in the presence or recurrent clinical symptoms
4. Further secondary endpoints
4.1. Wound healing documeted by serial photographs
4.2. Quality of life (PAVK 86, MOS-SF 36)
4.3. Total costs of treatment modalities

Overall study start date
01/10/2012

Completion date
30/09/2016

Reason abandoned (if study stopped)
"Participant recruitment issue": lack of recruitment of participants in previous phase of trial ISRCTN39997806, so this study was not started

Eligibility

Key inclusion criteria
1. Critical limb ischemia (CLI) lasting > 2 weeks (Fontaine stages III or IV or Rutherford classes 4 to 6 as assessed by clinical examination
2. Ankle pressure < 50 mm Hg, toe pressure <30 mm Hg, TcPo2 < 30 mm Hg
3. Availability of adequate saphenous vein for bypass surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
550

Key exclusion criteria
1. Acute limb-threatening ischemia (either embolic or thrombotic)
2. Non-atherosclerotic disease or documented hypercoagulopathy
3. End-stage renal disease and other severe co-morbidities with a life expectancy of less than 2 years American Society of Anesthesiologists [(ASA) IV, V]
4. Chronic total occlusions of the common/superficial femoral artery (>20cm) or the popliteal artery and proximal trifurcation vessels [according to TransAtlantic InterSociety (TASC) II D lesions]
5. Isolated single or multiple stenosis of the infrainguinal arteries that could be treated by endovascular means
6. Impaired infow of the aorto-iliac arteries (>50% stenosis or occlusions)
7. Contraindications for antiplatelet agents and/or anticoagulants
8. Surgical or catheter intervention on the index leg within the last 3 months

Date of first enrolment
01/10/2012

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Germany

Study participating centre
Clinic for Vascular Surgery
Munich
Germany
81675

Sponsor information

Organisation
Technical University of Munich [Technische Universitaet Muenchen] (Germany)

Sponsor details
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Ismaninger Str. 22
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Germany
81675

Sponsor type
University/education

Website
http://portal.mytum.de/

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation [Deutsche Forschungsgemeinschaft (DFG)] ref: 247

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