

# Angioplasty or bypass surgery in critical limb ischemia

<b>Submission date</b> 25/05/2011	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2012	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/01/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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 classification 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 documented 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 inflow 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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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