ISRCTN14469736 https://doi.org/10.1186/ISRCTN14469736

# The BASIL-3 Trial: Balloon vs. Stenting in Severe Ischaemia of the Leg-3

| | | |
|---|---|---|
| **Submission date**<br>21/10/2015 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>22/10/2015 | **Overall study status**<br>Completed | |
| **Last Edited**<br>25/02/2025 | **Condition category**<br>Circulatory System | |

## Plain English summary of protocol

Background and study aims

Severe limb ischaemia (SLI) is a growing problem in the UK, with one in every 1000-2000 people being diagnosed every year. SLI is a serious condition in which the arteries supplying limbs (most often the legs) with blood become narrowed or blocked due to the build-up of fatty substances (plaque). This often occurs around the knee in the femoral and popliteal arteries (femoropopliteal disease), which means that the lower parts of the limb (such as the feet) do not receive adequate blood supply (vascularisation). In SLI, small injuries to the feet are unable to heal, as they are not being supplied with enough oxygen rich blood. If left untreated, this can lead to ulcers, gangrene and ultimately death of the limb (necrosis). Once the limb “dies” the only available course of action is amputation, which can cause the sufferer a great deal of emotional distress. In recent years, more and more patients are undergoing surgery to improve blood supply to the leg (revascularisation) before amputation becomes the only option. An angioplasty is a common procedure in which a thin tube (catheter) is placed in the narrowed blood vessel. A small balloon on the tip of the catheter is gradually inflated to reopen the artery and flatten the blockage against the artery wall. In some cases, the surgeon may also insert a mesh-like tube (stent) into the artery to keep it open. These techniques are known as endovascular, as they take place inside the artery. In recent years, new techniques have been developed with incorporate drugs designed to stop the blockages coming back. These techniques can be very expensive however, and more research is needed to find out whether they are more effective in the long-term than traditional procedures. The aim of this study is to compare the effectiveness and cost-effectiveness of new endovascular techniques using drugs with traditional methods.

Who can participate?

Adults with severe limb ischaemia due to femoropopliteal disease, who are suitable for early revascularisation.

What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group are given a plain balloon angioplasty (traditional method), in which a bare metal stent (stent without a coating) is also inserted if required. For those in the second group, the balloon used in the angioplasty procedure is coated in a drug (drug-coated balloon angioplasty) designed to prevent

cells from multiplying (cell proliferation) and re-blocking the artery. During the angioplasty procedure, the medication on the balloon surface is deposited on the artery wall when the balloon inflates. Those in the third group have a drug-eluting stent (DES) placed in the artery, which is a stent that is coated in a drug that blocks cell proliferation. After their procedures, patients in all three groups are monitored to find out whether having the endovascular procedure has prevented the need for amputation.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2015 to August 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Suzanne Lockyer, BASIL-3@trials.bham.ac.uk

### Study website
https://www.birmingham.ac.uk/research/bctu/trials/portfolio-v/basil-3/index.aspx

## Contact information

### Type(s)
Public

### Contact name
Ms Suzanne Lockyer

### Contact details
The University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 415 8444
BASIL-3@trials.bham.ac.uk

## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
183761

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
19816

# Study information

### Scientific Title
Multi-centre randomised controlled trial of clinical and cost-effectiveness of drug coated balloons, drug eluting stents and plain balloon angioplasty with bail-out bare metal stent revascularisation strategies for severe limb ischaemia due to atherosclerotic femoro-popliteal, with or without infra-popliteal involvement, peripheral arterial disease

### Acronym
BASIL-3

### Study objectives
The aim of this study is to determine whether a drug coated balloon +/- bare metal stent or a drug eluting stent with plain balloon angioplasty or a bare metal stent are the most effective revascularisation strategy and the most clinically and cost-effective treatment strategy for severe limb ischaemia due to femoro-popliteal disease.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 26/08/2015, North of Scotland Research Ethics Committee (Summerfield House 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224558458; gram.nores@nhs.scot), ref: 15/NS/0070

### Study design
Randomized; Interventional; Design type: Treatment

### 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 to request a patient information sheet

### Health condition(s) or problem(s) studied
Severe limb ischaemia due to femoro-popliteal disease

### Interventions
Participants are randomly allocated to one of three treatment groups.

Group 1: Participants receive a plain balloon angioplasty with a bare metal stent (if needed)
Group 2: Participants receive a drug coated balloon with a bare metal stent (if needed)
Group 3: Participants receive a drug eluting stent

To fully capture this activity, as well as the associated changes in QoL and health resource usage, patients will be closely followed up, for a minimum of two years. Patients are asked to attend follow-up appointments at 1, 6, 12, 24 and 36 months. At each timepoint patients will be asked to complete questionnaires and some of their clinical data will be collected. After 3 years patients will be followed up for primary outcome only (i.e. if they are still alive and still have the trial limb).

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Amputation free survival (AFS) defined as the time to major limb (above the ankle) amputation of the index (trial) limb or death from any cause

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
15/11/2015

### Completion date
31/08/2023

## Eligibility

### Key inclusion criteria
1. Aged 18 years or over
2. Have severe limb ischaemia due to femoro-popliteal, with or without infra-popliteal, peripheral artery disease
3. Be judged by the responsible clinicians (consultant vascular surgeon, interventional radiologist, diabetologist) working as part of a multidisciplinary team to require early endovascular femoro-popliteal, with or without infra-popliteal revascularisation in addition to best medical treatment, foot and wound care
4. Have adequate ‘inflow’ to support all possible trial revascularisation strategies
5. Be judged suitable for all possible trial revascularisation strategies following diagnostic imaging and a formal (documented) discussion by a multi-disciplinary team meeting

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
480

### Total final enrolment
481

### Key exclusion criteria
1. Have an anticipated life expectancy <6 months
2. Are unable to provide consent due to incapacity (as defined by Mental Capacity Act 2005 or Adults with Incapacity [Scotland] Act 2000)
3. Are a non-English speaker where translation facilities are insufficient to guarantee informed consent
4. Are judged unsuitable for any of the revascularisation strategies being evaluated

### Date of first enrolment
15/11/2015

### Date of final enrolment
31/08/2021

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Clinical Trials Unit**
The University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

## Sponsor information

**Organisation**
University of Birmingham

**Sponsor details**
Department of Cardiovascular Medicine
Medical School
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

**Sponsor type**
University/education

**ROR**
https://ror.org/03angcq70

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**

Current publication and dissemination plan as of 18/08/2023:
Papers will be published following the analysis of the data. This will include a paper on the main trial results and a paper on the economic evaluation. A synopsis discussing all results will be published by NIHR (funder).

Previous publication and dissemination plan:
Papers will be published following the analysis of the data. A report to the HTA is required within 12 months of trial completion and will also be published.

## Intention to publish date
31/12/2024

## Individual participant data (IPD) sharing plan
Patient-level data will be made available within 6 months of publication. Requests for data generated during this study will be considered by BCTU (contact BASIL-3 trial office – BASIL-3@trials.bham.ac.uk). Requests will be assessed for scientific rigour before being granted. Data will be anonymised and securely transferred. A data-sharing agreement might be required.

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 19/05/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 24/02/2025 | 25/02/2025 | Yes | No |