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

Submission date
21/10/2015

Recruitment status
No longer recruiting

Registration date
22/10/2015

Overall study status
Completed

Last Edited
10/12/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
183761

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

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
United Kingdom

England

Study participating centre
Clinical Trials Unit
The University of Birmingham
Edgbaston
Birmingham
England
B15 2TT

Sponsor information

Organisation
University of Birmingham

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

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?
Results article		24/02/2025	25/02/2025	Yes	No
Results article		06/11/2025	10/12/2025	Yes	No
Protocol article	protocol	19/05/2017		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes