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BASIL-2: Bypass v Angioplasty in Severe Ischaemia of the Leg - 2

Submission date 07/05/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/05/2014	**Overall study status** Completed	
Last Edited 15/10/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
One in every 1000-2000 people in the UK will be diagnosed with advanced cases of Severe Limb Ischemia (SLI) yearly. As a result of a combination of smoking, diabetes, high blood pressure, high cholesterol levels, kidney failure and the ageing process, some people develop hardening of the arteries in their legs. In SLI, even minor injuries to the foot can fail to heal, resulting in the development of ulceration, even gangrene. Unless the blood supply to the leg and foot is improved, many people affected by SLI will lose their limb and/or die within 12 months. As well as causing great suffering, SLI places a large financial burden upon health and social care services. The two treatments currently available for SLI are vein bypass (VB) and best endovascular treatment (BET). In VB a vein is used to bypass the blockage. BET involves opening up the diseased arteries with balloons and sometimes the use of little metal tubes called stents. Both treatments have pros and cons and there is debate and uncertainty as to which is preferable, when, in which arteries, and in which patients.

Who can participate?
This study aims to recruit 600 adult patients with SLI from the participating hospitals.

What does the study involve?
Patients will be randomly allocated to receive either vein bypass surgery or the best endovascular treatment. Patients will be followed up clinically for 3 years and asked to complete questionnaires at 10 time points over this time. The 10 time points have been selected to occur at the same time as the patient would normally have a clinical appointment - there are no additional appointments.

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

Where is the study run from?
The study is run from about 40 hospitals within the British Isles.

When is the study starting and how long is it expected to run for?
May 2014 to April 2023

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK).

Who is the main contact?
Clinical Lead: Professor Andrew Bradbury, andrew.bradbury@btinternet.com
Administrative contact: Suzanne Lockyer, basil-2@trials.bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/bctu/trials/portfolio-v/basil-2/index.aspx

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/35/45

Study information

Scientific Title
Multicentre randomised controlled trial to compare the clinical and cost-effectiveness of a vein-bypass-first with an endovascular-first revascularisation strategy for severe limb ischaemia (SLI) due to infrageniculate arterial disease

Acronym
BASIL-2

Study objectives

The clinical and cost-effectiveness of a bypass-surgery-first strategy compared with an angioplasty-first strategy is superior for treating people with critical limb ischaemia caused by disease of the infra-popliteal arteries.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/123545

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES West Midlands (Coventry & Warwick); 03/03/2014; ref: 14/WM/0057

Study design
Randomised multicentre pragmatic two-arm open trial incorporating an internal pilot phase and within-trial health economic analysis

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
Severe ischaemia of the lower limb due to infrageniculate arterial disease

Interventions
The interventions are either vein bypass surgery or best endovascular treatment. Best endovascular treatment will involve balloon angioplasty and possibly the use of stents. Randomisation will be on a 1:1 basis, and patients will be followed up for 3 years with clinic visits at 1, 3, 6, 9, 12, 18, 24, 30, and 36 months post randomisation. These clinic visits coincide with the pattern of visits for standard practice.

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

1. Overall Survival (OS)
2. In-hospital and 30-day morbidity and mortality
3. Major Adverse Limb Event, defined as amputation (transtibial or above) or any major vascular re-intervention (thrombectomy, thrombolysis, balloon angioplasty, stenting, or surgery)
4. Major cardiovascular events (SLI and amputation affecting the contralateral limb, acute coronary syndrome, stroke)
5. Relief of ischaemic pain [visual analogue scale (VAS), medication usage]
6. Psychological morbidity [Hospital Anxiety and Depression Scale (HADS)]
7. Quality of life (QoL) using generic [EQ-5D-5L, SF-12, ICEpop CAPability measure for Older people (ICECAP-O)] and disease-specific (VascuQoL) tools
8. Re- and cross-over intervention rates
9. Healing of tissue loss (ulcers, gangrene) as assessed by the PEDIS and the WiFi scoring and classification systems
10. Extent and healing of minor (toe and forefoot) amputations (also using PEDIS and WiFi)
11. Haemodynamic changes; absolute ankle and toe pressures, ankle brachial pressure index (ABPI), toe brachial pressure index (TBPI)

Overall study start date
30/05/2014

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Have Severe Limb Ischaemia (SLI) due to infra-popliteal (IP), with or without femoro-popliteal (FP) disease
2. Be judged by the responsible clinicians (consultant vascular surgeon (VS), interventional radiologist (IR), diabetologists) working as part of a multi-disciplinary team (MDT) to require early infra-popliteal (IP), with or without femoro-popliteal (FP), revascularisation in addition to Best Medical Treatment (BMT), foot and wound care
3. Have Aorto-Iliac (AI) inflow adequate to support Vein Bypass (VB) and Best Endovascular Treatment (BET) (if not, then patients can be randomised after a successful AI procedure which can be either surgical or endovascular)
4. Be judged suitable for both Vein Bypass and Best Endovascular Treatment following diagnostic imaging and a formal (documented) discussion by consultant vascular surgeon and interventional radiologist in a properly constituted multi-disciplinary team meeting

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Total final enrolment
345

Key exclusion criteria
Patients will be excluded if they:
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 either of the two revascularisation strategies by the responsible consultant VS and IR

Date of first enrolment
30/05/2014

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Heart of England NHS Foundation Trust
Solihull
United Kingdom
B91 2JL

Sponsor information

Organisation
University of Birmingham (UK)

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Research Support Group
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK); ref. 12/35/45

Results and Publications

Publication and dissemination plan
The full trial report will be submitted to the funder (NIHR HTA) in June 2023 and subsequently published on its website.

Intention to publish date
30/04/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Requests for data generated during this study will be considered by BCTU (via ctudatashare@contacts.bham.ac.uk). Data will typically be available within six months after the primary publication unless it is not possible to share the data (for example: the trial results are to be used as part of a regulatory submission, the release of the data is subject to the approval of a third party who withholds their consent, or BCTU is not the controller of the data).
Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the Chief Investigator and, where appropriate (or in absence of the Chief Investigator) any of the following: the Trial Sponsor, the relevant Trial Management Group (TMG), and independent Trial Steering Committee (TSC).
A formal Data Sharing Agreement (DSA) may be required between respective organisations once release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers transfer of patient identifiable information. Any data transfer will use a secure and encrypted method.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/01/2016		Yes	No
Results article		24/04/2023	02/05/2023	Yes	No
Statistical Analysis Plan	version 2.0		02/05/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		01/10/2024	15/10/2024	Yes	No