

Comparing endovascular (keyhole) surgery with open surgery for the treatment of acute limb ischaemia (ALI) of the lower limb

Submission date 25/08/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/08/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 26/08/2026	Condition category Circulatory System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Acute limb ischaemia (ALI) is a common emergency condition. ALI occurs when the arteries supplying blood to the legs suddenly become blocked by a blood clot. Without blood flow to the legs, nerves, muscles and skin can die within hours, leading to amputation or death. Approximately one in ten people treated for ALI in the NHS die in hospital within a few days, and around four in ten die within one year. ALI is one of the most common causes of amputation in the NHS.

In people with ALI, treatment involves an emergency procedure to unblock the affected artery. This can be performed using either open surgery or keyhole (endovascular) surgery. Open surgery requires a skin incision to open the affected artery and remove or bypass the clot. Keyhole surgery can be performed under local anaesthetic and requires only small needle punctures. It is unclear which treatment approach is more effective at preventing amputations and deaths, or which provides better value for money for the NHS. This study aims to address this uncertainty and determine which treatment option is more effective.

The aim of this research is to determine whether open surgery is more effective than keyhole (endovascular) surgery for treating people with ALI of the leg in terms of preventing death, amputation and hospital readmissions over six months.

Who can participate?

Adults aged 18 years and over with ALI of the lower limb can participate.

What does the study involve?

Participants are randomly allocated to receive either open surgery or keyhole (endovascular) surgery to treat their ALI. Random allocation means that neither the participant nor their clinical team chooses which surgical treatment is received. Participants are allocated to one of the following groups:

- Open surgery for the treatment of ALI
- Keyhole (endovascular) surgery for the treatment of ALI

Participants are followed up for six months. Most study data are collected from medical records. Following surgery, participants attend two clinic appointments, one at 30 days and one at six months, for vascular assessments that form part of routine NHS care after these procedures. These visits usually last approximately 30 minutes. Participants are also asked to complete questionnaires at 30 days and six months covering quality of life, symptoms and any additional treatments received.

What are the possible benefits and risks of participating?

Participants may not receive a direct personal benefit from taking part. However, participation contributes to improving the treatment of future patients with ALI. The study findings may help inform the planning and delivery of effective NHS services in the future.

Participation helps evaluate open and keyhole surgery for ALI and is not expected to involve additional risk. All procedures and techniques used in the study are already established NHS treatments for ALI. Regardless of treatment allocation, surgery is performed by appropriately trained and competent clinicians.

Where is the study run from?

The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

September 2026 to March 2029

Who is funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (UK).

Who is the main contact?

Dr Lynda Constable (establish@abdn.ac.uk)

Contact information

Type(s)

Scientific, Public

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Additional identifiers**Integrated Research Application System (IRAS)**

347905

Central Portfolio Management System (CPMS)

64354

National Institute for Health and Care Research (NIHR)

167680

Study information**Scientific Title**

Endovascular strategy versus Surgical strategy for the Treatment of Acute Limb Ischaemia of the lower limb

Acronym

ESTABLISH

Study objectives

Primary objective:

To compare open surgical revascularisation strategy to endovascular revascularisation strategy in terms of amputation-free survival at 6-months

Secondary objectives:

To compare open surgical revascularisation strategy to endovascular revascularisation strategy in terms of mortality, lower limb amputation, re-interventions, duration of hospital stay and hospital re-admissions, cardiovascular events, cardiovascular medications and quality-of-life up to 6 months after randomisation. Additionally, to estimate the relative cost-effectiveness to the NHS and personal social services (PSS) of the two approaches

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 29/07/2026, West of Scotland REC 5 (West of Scotland Research Ethics Service, Level 2, Administration Building, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 141 314 0213; ggc.wosrec5@nhs.scot), ref: 26/WS/0110

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Single

Purpose

Treatment

Study type(s)**Health condition(s) or problem(s) studied**

Acute limb ischaemia of the lower limb

Interventions

Randomisation will occur after all eligibility criteria are confirmed, and after verbal or fully informed consent has been obtained. Participants will be randomised in a 1:1 ratio to either open surgical strategy or endovascular strategy using a remote central, computer-generated minimisation algorithm hosted by CHaRT. The minimisation variables are age (<50, 50-69, 70+ years), sex (male, female), centre, clinical frailty score (≤ 3 not frail, > 3 frail), and disease condition (unilateral, bilateral). Given the urgent nature of ALI, we anticipate that the intervention will take place within 48 hours of randomisation in most cases, however we are not stipulating the timing of intervention from randomisation – we expect procedures to take place as promptly as clinically appropriate, as decided by the treating clinicians and local practice.

Participants will be asked to complete a short baseline questionnaire prior to knowing their randomised allocation.

Due to the nature of the interventions, there is no blinding of site staff or participants.

The intervention (open or endovascular strategy) to treat their ALI will be undertaken, as part of usual clinical practice.

Participants will have clinical vascular assessments as per NHS standard of care at 30 days and 6 months after randomisation (this usually lasts around 30 minutes). Participant reported outcome measures (EQ-5D-5L and VasculQoL-6) will be collected at baseline, 30 days and 6 months after randomisation.

Intervention Type

Other

Primary outcome(s)

Death and/or major amputation (defined as time to death and/or ipsilateral major (above ankle) lower limb amputation) measured using medical records/patient report at up to six months post randomisation (30 days and 6 months)

Key secondary outcome(s)

1. Major lower limb amputation measured using medical records up to six months post randomisation (30 days and 6 months)
2. Number and timing of any subsequent interventions or readmissions measured using medical records and patient report at 30 days and 6 months
3. Minor lower limb amputations (below ankle) measured using medical records at 30 days and 6 months
4. All-cause mortality measured using medical records at 30 days and 6 months
5. Number and time to any cardiovascular event measured using medical records and patient report at 30 days and 6 months
6. Duration of hospital stay measured using medical records at 30 days and 6 months
7. Discharge location measured using medical records and patient report at 30 days and 6 months
8. Number of hospital admissions measured using medical records and patient report at 30 days and 6 months
9. Use of post-revascularisation cardiovascular medications measured using medical records and patient report at 30 days and 6 months
10. Quality of life measured using EQ-5D-5L and VasculQoL-6 (patient reported) at baseline, 30 days and 6 months
11. Healthcare use and costs over the trial follow-up measured using medical records and patient report at surgery, 30 days and 6 months

Completion date

31/03/2029

Eligibility

Key inclusion criteria

1. Adults aged 18 years and over
2. ALI of the lower limb (all-comers i.e. embolic and thrombosis in situ and bilateral presentation (with allocation to the treatment strategy at the participant level, see Protocol section 4.4) suitable for open or endovascular intervention, and requiring revascularisation as deemed appropriate by the treating clinicians
3. Able and willing to give informed consent to participate and to participate in study procedures

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

120 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Not suitable for open repair or endovascular surgery (technical or clinical rationale)
2. Non-salvageable limb
3. Current pregnancy or lactation
4. Allergy to contrast agent(s)
5. People who do not have the capacity to consent for themselves

Date of first enrolment

01/09/2026

Date of final enrolment

30/06/2028

Locations**Countries of recruitment**

United Kingdom

England

Scotland

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

England

NE7 7DN

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
England
W2 1BL

Study participating centre
NHS Humber and North Yorkshire Integrated Care Board
2nd Floor
Wilberforce Court
Alfred Gelder Street
Hull
England
HU1 1UY

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
England
GU16 7UJ

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
England
YO31 8HE

Study participating centre

NHS Lothian

Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Study participating centre

Manchester University NHS Foundation Trust

Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre

University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre

Somerset NHS Foundation Trust

Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
England
TA1 5DA

Study participating centre

Royal Free London NHS Foundation Trust

Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
London North West University Healthcare NHS Trust
Northwick Park Hospital
Watford Road
Harrow
England
HA1 3UJ

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
England
GL53 7AN

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Study participating centre

Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Study participating centre

Northampton General Hospital NHS Trust
Cliftonville
Northampton
England
NN1 5BD

Study participating centre

Tayside
Ninewells Hospital
Dundee
Scotland
DD1 9SY

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care 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**IPD sharing plan summary**

Data sharing statement to be made available at a later date