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A study comparing minimally invasive (endovascular) treatment and open surgery to improve blood flow in the groin (femoral) artery

Submission date
24/04/2026

Recruitment status
Not yet recruiting

Registration date
08/06/2026

Overall study status
Ongoing

Last Edited
08/06/2026

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
One in five people over 55 years have blockages in arteries carrying blood to the legs. Poor blood flow due to these blockages can cause leg pain or gangrene. When someone has these symptoms, they need an operation to improve blood flow. This is done by opening up the blocked arteries. The leg artery that most often needs unblocking is an artery in the groin called the femoral artery. Doctors have been treating narrowed or blocked femoral arteries with open surgery for years. This open surgery often leads to problems like wound infections, pain, and a long stay in hospital. Recently, keyhole surgery has been developed for such cases, which is less invasive, performed under local anaesthetic, and might lead to fewer complications and better quality of life. Keyhole surgery is now often performed in the NHS for diseased femoral arteries. Unfortunately, we don't know whether open or keyhole surgery is better. Both surgeries have pros and cons. By finding out which is better, we may be able to reduce the number of amputations, deaths, and additional surgeries for people with femoral artery disease. Also, we will find out which surgery costs the NHS less money.
This study will check whether open or keyhole surgery of the common femoral artery is better at preventing amputations, deaths, and additional leg surgeries. We will also check the quality of life of people taking part and which type of surgery is cheaper for the NHS.

Who can participate?
Patients aged 18 years and over with chronic limb-threatening ischemia (CLTI) who are suitable for open or endovascular methods of revascularisation.

What does the study involve?
Participants will be randomly allocated to open or endovascular treatment. After their procedure, a follow-up period will assess their clinical outcomes, quality of life and cost-effectiveness of the care received. The follow-up period lasts a maximum of 36 months post-procedure with a minimum follow-up period of 12 months.

What are the possible benefits and risks of participating?
Taking part may offer several possible benefits. Participants will receive either open surgery or

minimally invasive (endovascular) treatment, both of which are standard treatments already used in the NHS. They will be closely monitored by a specialist vascular team, with regular follow-up to check recovery, blood flow to the leg, and quality of life. The information collected may help doctors understand which treatment works best, which could improve care for future patients with peripheral arterial disease.
There are also possible risks. As with any operation or procedure, complications can occur. Open surgery may involve a larger cut, more pain, wound infection, or a longer stay in hospital. Minimally invasive treatment is less invasive but may not last as long, and some people may need further procedures in the future. Taking part may also involve extra clinic visits or questionnaires. All risks will be explained before participation.

Where is the study run from?
1. University Hospitals of Leicester (UK)
2. University of Leicester (UK)

When is the study starting and how long is expected to run for?
July 2026 to November 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) (UK)

Who is the main contact?
1. Prof. Athanasios Saratzis, as875@leicester.ac.uk
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Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
341975

Central Portfolio Management System (CPMS)
61599

National Institute for Health and Care Research (NIHR)
167450

Study information

Scientific Title
A RAndomised controlled trial assessing the clinical and cost-effectiveness of endovascular vs open revascularisation for common Femoral artery steno-occlusive disease: the RAF trial

Acronym
RAF

Study objectives
Primary objective:
Identify whether open surgery for CFA disease is superior to endovascular treatment in terms of death and re-interventions (including major amputation or arterial revascularisation) over a minimum 1-year follow-up in a time-to-event analysis.

Secondary objectives:
1. Estimate differences in quality of life of patients between arms.
2. Estimate differences in quality-adjusted life years (QALYs) and costs between two arms.
3. Evaluate the incremental cost-effectiveness ratios in terms of clinical improvement and QALYs gained of the intervention group compared with the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 23/04/2026, South Central - Oxford B Research Ethics Committee (N/A, Oxford, N/A, United Kingdom; N/A; oxfordb.rec@hra.nhs.uk), ref: 26/SC/0158

Study design
Multicentre prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment, Other

Health condition(s) or problem(s) studied
Revascularisation for common femoral artery steno-occlusive disease

Interventions
Randomisation is 1:1 and performed through a web-based service called Sealed Envelope. Participants are randomised to undergo either open surgery or endovascular treatment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Composite of death (all-cause) and/or reintervention (major amputation or lower limb revascularisation) is measured over a minimum of 1 year (time-to-event analysis). Major amputation is defined as any amputation above the level of the ankle joint in the ipsilateral lower limb. Revascularisation is defined as any arterial revascularisation in the ipsilateral lower limb.

Key secondary outcome(s))
1. Quality of life measured using the EuroQOL-5D (EQ-5D-5L) score at baseline and months 6, 12, 24 and 36
2. Mortality (all causes), measured using information from medical records and local trust systems, causes of death and death certificate information will be collected within study CRFs by the local research team. Main timepoints: day of discharge, 30 days post, 6, 12, 24, 36 months and final assessment.
3. Hospital admissions (including reason for admission), reinterventions (including nature of reintervention) and all lower limb amputations (minor and major, i.e., below and above the ankle joint), measured using information from medical records and local trust systems, including procedural details. This can be a separate event at 6, 12, 24 and 36 months (or final assessment) for those that don't complete full follow-up by the end of the trial.
4. Healthcare resource-use and costs (participant medical notes). Review of medical notes will be used to ensure capture of postoperative appointments in primary/community care. Further, telephone remote follow-up (centrally) will be used to capture missing information regarding amputations, reinterventions, readmissions, and mortality (relating to the primary outcome). Resource use is measured at 6, 12, 24 and 36 months; costs will be pulled from procedural information which could be a separate event (re-intervention) but is captured at the follow-up points listed above unless the research team is made aware between follow-up points an event (admission/re-intervention/death) may occur.

Completion date
30/11/2029

Eligibility

Key inclusion criteria

1. Age >=18 years
2. Chronic limb-threatening ischemia (CLTI) (rest pain and/or tissue loss) or severe lifestyle-limiting claudication (Rutherford Stage >=3 or Fontaine Stage >=IIb)
3. Patient deemed suitable for common femoral artery (CFA) open surgery or endovascular treatment by the treating clinicians (pragmatic design)

For participants with bilateral disease, the leg with more severe symptoms will be designated as the trial leg, as per other RCTs. Adjunctive inflow/outflow procedures will be permitted, with decisions regarding these left to the discretion of operators (pragmatic design).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Asymptomatic peripheral artery disease (PAD)
2. Pregnancy

Date of first enrolment
01/07/2026

Date of final enrolment
30/06/2028

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
University Hospital of Leicester
Infirmary Square
Leicester
England
LE1 5WW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Not defined

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