ISRCTN14591444 https://doi.org/10.1186/ISRCTN14591444

Is the clinical and cost-effectiveness of open surgery for severe occlusive disease of the aorta and iliac arteries superior to newer endovascular (keyhole) treatment? The EVOCC Trial

Submission date	**Recruitment status**	[X] Prospectively registered
13/07/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/10/2025	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Lower limb Peripheral Arterial Disease (PAD) is a form of severe occlusive aorto-iliac disease which affects one in five people over 55 years of age in the UK and is the main cause of leg amputations in the NHS. This is caused by blockages or narrowings in the arteries carrying blood to the leg(s). Some sufferers may develop leg pain when walking whereas others might have leg pain at rest or death of the tissue in the leg(s). This can be leg and life threatening and must be treated with surgery to save the leg or life. The surgery can use one of two common ways of getting more blood to the leg(s):

• Open surgery: this involves an operation to bypass the blocked/narrowed arteries

• Keyhole surgery: this involves inflating a balloon inside the blocked/narrowed arteries forcing them to open (angioplasty). Sometimes it is necessary to put a small metal tube into the artery to hold it open (stenting). This type of procedure is called endovascular treatment

Both open and keyhole surgery are currently offered to patients in the NHS.

This trial aims to understand which type of surgery is better for saving the legs and lives of patients with PAD, which type is less likely to lead to more surgery in the future and which is better cost-wise for the NHS.

Who can participate?

Adults aged over 18 years with PAD

What does the study involve?

You will be required to attend 7 visits (including your surgery) spread over 24 months, with the remaining 3 visits being remote and taking place either over the telephone or by using information from your medical records (10 visits in total). The 3 remote visits will take place between 24 and 54 months after your surgery.

The tests and questionnaires that you will be asked to undergo at the different visits are

detailed in the table below along with the approximate length of time each visit will take. The scheduled trial visits, as detailed below, will match the same care and number of visits that you would normally receive after this type of surgery. You won't be required to visit your hospital any more than you normally would.

What are the possible benefits and risks of participating?
Whilst there are no direct benefits in taking part, you may potentially benefit from better follow-up after you have the procedure to open the blocked or narrowed arteries. Given that the trial team will be in touch with you to find out how your health is, you might receive more regular care compared to someone who has not taken part in the research.

Keyhole Surgery
The potential risks of keyhole surgery can be divided into the following categories:
Related to arterial puncture site (usually in the groin):
• Bruising, this is inevitable but usually goes away in a few weeks
• Pain, this is inevitable but it is not usually severe and can be well controlled with medication
• Bleeding, again this is inevitable but it is usually fairly minimal and stops of its own accord fairly quickly
• Rarely (1%) significant bleeding at the puncture site can require an emergency operation to repair the damaged artery
Related to the contrast (the dye put into your arteries so that they can be seen by X-rays):
• Some patients experience an allergic reaction to the X-ray contrast. In most cases this is minor but rarely, the reaction may be severe and require urgent treatment with medicines. Very rarely it can be fatal.
• The x-ray contrast can, in some patients, affect kidney function. If you are likely to be at risk of this, special precautions will be taken to reduce the chances of this problem occurring. Rarely, damage from the contrast can lead to the patient being put on a kidney machine (for dialysis). This is usually temporary but very rarely can be permanent.
Related to the treatment:
• The procedure may not work because the diseased arteries cannot be opened up with balloons and stents. In previous similar studies, this has occurred in up to 10-20% of patients. We do not know how often this will happen in this trial but the risks may be similar. If the procedure fails, your consultants may suggest having another go at angioplasty/stenting on a different day, or they may suggest going on to have open surgery instead.
• Rarely, the angioplasty/stenting procedure can lead to a worsening of the blood supply to the leg so that emergency surgery is required to prevent amputation.
• Rarely, the angioplasty/stenting procedure can lead to the blocked/narrowed artery bursting. This can sometimes be treated in the x-ray department by putting in a special stent with a covering around it (a stent-graft). If this is not possible, an emergency operation may be required to repair the artery.
• Rarely, small fragments from the lining of the blocked / narrowed artery can break off and lodge in an artery further down the leg. This may also require an operation to 'fish out' the fragments if they are causing a problem with the blood flow.
Related to the radiation risk:
• The angiography and stenting procedure is part of your routine care. If you take part in this trial, you will not undergo any additional examinations. These procedures use ionising radiation to form images of your body and provide your doctor with other information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this trial or not.

Open Surgery
The potential risks of open surgery can be divided into the following categories.

Related to anaesthetic:
Open surgery is usually performed with you asleep under general anaesthesia although sometimes it is performed with you awake with the lower half of your body numbed by an injection in your back (epidural or spinal anaesthesia). These days such anaesthetics are very safe but the following problems can occur:
• Feeling sick and vomiting, this is quite common but is usually well controlled by tablets or injections
• Rarely, there can be damage to teeth / dentures from the tube put down your throat to help you breathe
• Rarely, lung problems can occur such as pneumonia (inflammation of the lungs, usually caused by an infection) or a collapsed lung
• Muscle aches and pain can occur but usually get better in a few days of their own accord
• Confusion, this is uncommon and usually clears in a few days of its own accord
Related to the surgery itself:
• Rarely, the procedure may not work or fail soon after the operation.
• Wound problems can occur such as poor healing, bruising, bleeding and infection; in most cases these respond to good nursing care and antibiotics; rarely is further surgery required.
• As with any surgical procedure, you will feel somewhat tired afterwards and have some pain along the incisions; however, the pain is usually well controlled with tablets or injections.

Risks shared by both keyhole and open surgery
Many people with blocked arteries also have other significant health problems such as diabetes, heart and lung disease. For this reason, even if the procedures go well, there are some complications that can occur both after open surgery and keyhole surgery. Each of these individual complications is quite uncommon but taken together the overall risk is probably in the region of 5-10%.
These potential complications include:
• Stroke
• Heart attack
• Chest infection
• Drop in kidney function
• Bowel problems such as constipation, diarrhoea, poor blood supply to bowel
• Blood clots in the leg (deep vein thrombosis, DVT) and lung (pulmonary embolus, PE); these would require treatment with blood-thinning injections and then tablets

Participating in this trial will involve either keyhole or open surgery. You would receive one or the other of these procedures as normal clinical care anyway, but in this trial this choice is made for you by a computer system, rather than your clinician making the decision.
Your doctors will be able to discuss the nature and level of these risks to you in more detail in relation to your particular health problems. However, your doctors feel that one or the other of these treatments is necessary for you (whether you are in the trial or not) in order to prevent your leg getting worse to a point where you might require an amputation, or the condition may even become life-threatening.

Assessments
As part of the blood tests, you may experience some mild discomfort and occasionally slight bruising to the surface of the skin as a result of the venepuncture procedure (the process of drawing blood from a vein using a needle).

Performance of the Ankle Brachial Pressure Index should be relatively pain free although you may experience some temporary tightness or squeezing where the inflatable cuff is placed.

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

When is the study starting and how long is it expected to run for?
May 2023 to September 2028

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

Who is the main contact?
evocc@leicester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Carla Richardson

Contact details
-
-
United Kingdom
-
-
evocc@leicester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
323392

Central Portfolio Management System (CPMS)
56385

National Institute for Health and Care Research (NIHR)
151230

Study information

Scientific Title
A randomised controlled trial assessing the clinical and cost-effectiveness of Endovascular vs. Open revascularisation in severe oCClusive aorto-iliac disease. The EVOCC Trial

Acronym
EVOCC

Study objectives

The EVOCC trial is a two-arm prospective, superiority, multicentre (national), randomized controlled trial (RCT) comparing two modes of treatment which are already routine NHS care, in approximately 30 UK sites. Open surgery will be compared to the newer treatment (intervention) using established methodology and pre-specified plans. This will address the existing uncertainty whether surgery is superior (clinical and cost-effectiveness) to endovascular treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/05/2023, South West- Cornwall & Plymouth Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square , Bristol, BS1 6PN, United Kingdom; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 23/SW/0065

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe occlusive aorto-iliac disease

Interventions
Thirty NHS hospitals serving people with diverse ethnicities, social and economic backgrounds will take part. The researchers will ask people who need surgery to unblock their aorta or iliac arteries in these hospitals to participate in the trial, once they explain treatment options. Those who take part will be chosen at random to have either open or keyhole surgery. The researchers will then look at what happened to these people for an average of 3 years after surgery. They will compare the number of amputations, complications and deaths between those who had open and keyhole surgery. They will check people’s quality of life regularly and record all NHS care costs.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 05/09/2025:

Amputation-free survival (time to death or major lower limb amputation) measured in days from randomisation until first event or until the end of the trial (minimum 2 years)

———

Previous primary outcome measure:

1. Mortality (all cause), measured in days from randomisation until first event or until the end of the trial (minimum 2 years) where no event occurs
2. Cardiovascular events (myocardial infarction, stroke, admission for heart failure), measured in days from randomisation until first event or until the end of the trial (minimum 2 years) where no event occurs
3. Number of hospital admissions (including reasons for readmissions), following discharge from index surgical admission for up to 4.5 years at 6 and 12 months and annually thereafter.
4. All lower limb amputations (minor and major i.e. below and above ankle joint) measured in days from randomisation until first event or until the end of the trial (minimum 2 years) where no event occurs at baseline, trial intervention visit and day of discharge visit and all follow up visits (30 days, 6 and 12 months and annually thereafter)
5. Concomitant medications (specifically: use of statin, use of antithrombotic medication) at day of discharge, 30 days, 6 and 12 months and annually thereafter.
6. Estimated glomerular filtration rate (renal function) based on serum creatinine levels using the Chronic Kidney Disease Epidemiology (CKD-EPI) formula measured at 6 and 12 months and annually thereafter.
7. Low Density Lipoprotein measured at baseline and 6 months follow up visit.
8. HbA1C measured at baseline and 6 months follow up visit.
9. Cholesterol measured at baseline and 6 months follow up visit.
10. Ankle Brachial Pressure Index (ABPI) measured at baseline, 6 and 12 months and annually thereafter.
11. Types of endovascular devices used and/or name of surgery performed (open) at trial intervention visit and day of discharge.
12. Quality of life measured using the EQ-5D-5L measured at 6 and 12 months and annually thereafter.
13. Healthcare resource use and costs measured across follow-up assessments over a minimum of 24 months and until the end of the trial.

Key secondary outcome(s)

1. Mortality (all-cause), measured in days from randomisation until the first event or until the end of the trial (minimum 2 years) where no event occurs
2. Cardiovascular events (myocardial infarction, stroke, admission for heart failure), measured in days from randomisation until the first event or until the end of the trial (minimum 2 years) where no event occurs
3. Number of hospital admissions (including reasons for readmissions), following discharge from index surgical admission for up to 4.5 years at 6 and 12 months and annually thereafter.
4. All lower limb amputations (minor and major i.e. below and above ankle joint) measured in days from randomisation until the first event or until the end of the trial (minimum 2 years) where no event occurs at baseline, trial intervention visit and day of discharge visit and all follow up visits (30 days, 6 and 12 months and annually thereafter)
5. Concomitant medications (specifically: use of statin, use of antithrombotic medication) at the day of discharge, 30 days, 6 and 12 months and annually thereafter.
6. Estimated glomerular filtration rate (renal function) based on serum creatinine levels using the Chronic Kidney Disease Epidemiology (CKD-EPI) formula measured at 6 and 12 months and annually thereafter
7. Low Density Lipoprotein measured using standard blood sample assessments (standard of care, not research) at baseline and 6 months follow-up visit
8. HbA1C measured using standard blood sample assessments (standard of care, not research) at baseline and 6 months follow-up visit
9. Cholesterol measured using standard blood sample assessments (standard of care, not

research) at baseline and 6 months follow-up visit
10. Ankle Brachial Pressure Index (ABPI) measured using a sphygmomanometer and a hand-held Doppler device at baseline, 6 and 12 months and annually up to month 54
11. Types of endovascular devices used and/or name of surgery performed (open) recorded at trial intervention visit and day of discharge
12. Quality of life measured using the EQ-5D-5L measured at 6 and 12 months and annually thereafter
13. Healthcare resource use and costs measured using economic evaluation led by Health Economists with considerable experience in NIHR HTA-funded vascular research across follow-up assessments over a minimum of 24 months and until the end of the trial

Completion date
30/09/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/09/2025:

1. Adults (≥18 years) with symptomatic PAD (rest pain, tissue loss, or lifestyle-limiting claudication)
2. Severe aorto-iliac occlusive disease (TASC II C/D)
3. MDT consensus that both surgical and endovascular options are viable
4. Ability to provide informed consent
5. Ability to understand written English or availability of a translator to explain the trial documentation

———

Previous inclusion criteria:

Main Trial
1. Age > = 18 years (no upper age limit)
2. Presence of symptomatic PAD (tissue loss and/or rest pain and/or lifestyle limiting claudication)
3. Severe aorto-iliac occlusive PAD defined as “Inter-Society Consensus for the Management of Peripheral Arterial Disease” (TASC II) class C or class D
4. Patient discussed in a local vascular Multi-Disciplinary Team (MDT) meeting and deemed suitable for open surgery or endovascular treatment.
5. Patient willing and able to give consent and commit to study follow-up.
6. An ability to understand written English or availability of a translator to explain the trial documentation

Communication Study (Patients)
1. Patient willing and able to give consent
2. An ability to understand written English or availability of a translator to explain the study documentation
3. Involved with research visits with nurses and/or doctors that have provided consent for the HCP Communication Study (where related to audio-recording of research visits)

Communication Study (Healthcare Providers)
1. Willing and able to give consent
2. Involved with research visits with patients that have provided consent for the Communication Study (where related to audio-recording of research visits)

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 05/09/2025:

1. Asymptomatic PAD
2. Non-consent
3. Comorbid conditions precluding intervention

_____

Previous exclusion criteria:

Allergy to iodinated intravascular contrast agent including: Iopromide, Iodamide, Iohexol, ioversol, Ioxilan, Iopamidole.

Date of first enrolment
01/10/2023

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
St James's University Hospital
Gledow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Glenfield General Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
Royal Free Hospital
Royal Free Hospital
Pond Street
London

United Kingdom
NW3 2QG

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
St Thomas' Hospital
St. Thomas's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road

Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the statisticians at the CTU are responsible for data analysis and the parties as described here must remain independent and blinded to the raw data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/10/2025	20/10/2025	Yes	No
HRA research summary			20/09/2023	No	No