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Intravascular lithotripsy as the primary treatment strategy for calcified Iliac vessels

Submission date
18/06/2026

Recruitment status
Recruiting

Registration date
09/07/2026

Overall study status
Ongoing

Last Edited
17/08/2026

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Peripheral arterial disease (PAD) is a common condition in which blood flow to the legs is reduced because arteries become narrowed by fatty deposits and calcium. This can cause pain when walking and, in severe cases, constant pain, ulcers, or gangrene and may ultimately lead to amputation. PAD is also linked with a high risk of heart attack and stroke. Treating blocked arteries effectively is therefore very important for both limb health and overall survival. One commonly used treatment is angioplasty, where a balloon is inflated inside the artery to improve blood flow, sometimes followed by insertion of a metal stent. However, heavy calcium within the artery wall makes treatment more difficult and increases the chance that the artery will narrow again. Intravascular lithotripsy (IVL) is a newer technique that uses controlled sound waves delivered through a balloon to crack calcium within the artery, making it easier to open the vessel safely. IVL is already approved for use in the UK and Europe and is part of routine NHS care for selected patients. Newer IVL devices designed for larger arteries, such as those in the pelvis (iliac arteries) and the lower part of the aorta, are increasingly being used, but there is limited information about their longer-term safety, effectiveness, and costs in everyday clinical practice. The study will assess how safe and effective IVL is, how often further procedures are needed, rates of complications or hospital readmissions, and basic information on treatment costs. The findings will help patients, clinicians and the NHS understand the benefits, risks and value of IVL in this group of patients and guide future care.

Who can participate?
Adults aged 18 years and over with a diagnosis of PAD with the presence of calcified narrowing or blockage of arteries supplying blood to the pelvis or lower part of the main body artery, as confirmed by clinical imaging. They must either have already had routine IVL L6 treatment at a participating hospital site or be identified to undergo IVL L6 treatment as part of their usual clinical care.

What does the study involve?
The IVL study is a non-interventional study which collects intravascular lithotripsy (IVL) L6 treatment information from medical records and routine follow-up appointments after the treatment. There are also additional telephone follow-up appointments over a period of 12 months.

What are the possible benefits and risks of participating?
There is no direct therapeutic benefit to participants, but the study offers important indirect and societal benefits through contributing to knowledge that may improve outcomes for patients with peripheral arterial disease in the future. As such, participation in the research does not expose patients to additional clinical risk beyond standard care. Potential risks could be inconvenience related to follow-up contact, but this will be primarily telephone-based.

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 2026 to December 2034

Who is funding the study?
Shockwave Medical (USA)

Who is the main contact?
ivll6@leicester.ac.uk

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Prof Athanasios Saratzis

Contact details
University of Leicester
Glenfield Hospital
Cardiovascular Research Facility
Leicester
United Kingdom
LE3 QRP
+44 (0)1162523190
as875@leicester.ac.uk

Type(s)
Public

Contact name
None Shared Mailbox

Contact details
University of Leicester
Glenfield Hospital
Cardiovascular Research Facility
Leicester
United Kingdom
LE3 QRP

-
ivll6@leicester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
350518

Central Portfolio Management System (CPMS)
65196

Study information

Scientific Title
Intravascular lithotripsy as the primary treatment strategy for calcified Iliac vessels

Acronym
IVL L6

Study objectives
The main aim of this study is to find out how safe and efficacious a treatment called intravascular lithotripsy (IVL) is when it is used as the main treatment for people with blocked and heavily calcified arteries in the pelvis (iliac arteries) and the lower part of the main body artery (the aorta). Specifically, the study asks: When IVL is used in routine hospital care for people with peripheral arterial disease, how well does it open these arteries, how long do they stay open, and how often do patients need further treatment or experience complications over the following year? By following patients for up to 12 months after their usual IVL treatment, the study also aims to understand how often people are readmitted to hospital, whether they need further procedures, and whether any serious limb or heart related problems occur. In addition, the study will collect basic information about the costs of treatment in everyday clinical practice. Answering this question will help patients, doctors and the NHS understand whether IVL is a safe, effective and worthwhile treatment option for this group of patients and will support better decision-making about future care. In addition to the main aim, the study seeks to answer several related questions that are important to patients, clinicians and the NHS. First, the study will look at whether people who receive intravascular lithotripsy (IVL) need to return to hospital within a year because of problems related to their circulation, such as worsening leg symptoms, further blockage of the artery, or the need for another procedure. This includes understanding how often serious limb problems, such as ulcers, severe pain or amputation, occur after treatment. Second, the study will examine whether patients are admitted to hospital for other health problems in the year after treatment, including heart- or stroke-related events, as people with peripheral arterial disease are at higher risk of these conditions. Third, the study will assess how often any complications or side effects occur after IVL when it is used in everyday clinical practice and how these are managed as part of routine care. Finally, the study will collect basic information about the resources used during treatment, such as the number of devices required and whether additional treatments like stents are needed. This will help estimate the overall cost of care and understand whether IVL may reduce the need for further procedures.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/02/2026, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8083; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 26/NE/0033

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Calcified Iliac vessels

Interventions
This is an observational study, which means it does not change the care that patients receive. Everyone taking part will already have received intravascular lithotripsy (IVL) as part of their normal treatment for blocked and calcified arteries. The study simply collects information about what happens AFTER this treatment has taken place.

Before treatment (screening and consent):
Patients will be identified from routine clinic visits, hospital wards or operating lists. If they are interested, they will be given written information about the study and time to consider it. If they agree to take part, they will sign a consent form.
No tests or procedures are done just for the study.

At the time of treatment (day 0):
The IVL procedure is carried out exactly as planned by the clinical team, following normal hospital practice. The study team records information that is already routinely collected, such as details of the artery treated, the devices used, and whether the artery is successfully opened at the end of the procedure.

After treatment (follow-up):
Participants are followed up for up to 12 months. Information is collected at approximately:
1. 30 days
2. 3 months
3. 6 months
4. 12 months

Most follow-up is done by reviewing medical records and by short telephone calls with the participant. These calls ask about recovery, any hospital admissions, further procedures, or new health problems. If participants attend hospital clinics or have scans as part of normal care, those results are also recorded.

The only difference from standard care is the follow-up telephone calls by the research team. No extra hospital visits, scans or treatments are required for the study. No one will receive additional radiation or any other intervention (e.g., surgery or extra treatment) if they take part in the research.

The study records how well the artery stays open, whether further treatment is needed, any complications or hospital admissions, and basic information about treatment costs.

Overall, the study follows patients through their normal care pathway, with minimal extra involvement, to better understand how IVL works in everyday practice.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Freedom from major adverse limb events (MALE), defined as a composite outcome including major (above-ankle) lower limb amputation of the target limb, and/or clinically driven target limb reintervention, measured using routinely collected clinical data and standard follow-up, reflecting real-world NHS practice, at 12 months following the index intravascular lithotripsy (IVL) procedure

Key secondary outcome(s)
1. Major adverse limb events (MALE) at 30 days and 6 months following the index IVL procedure
2. All-cause mortality at 30 days, 6 months, and 12 months
3. Major adverse cardiovascular events (MACE): composite of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke at 12 months
4. Limb salvage: freedom from major (above-ankle) amputation of the target limb at 12 months
5. Target limb reintervention: rate and timing of clinically driven reintervention to the target limb within 12 months
6. Procedural success as recorded in routine clinical documentation, gathered on an ongoing basis whilst the participant is in follow-up
7. In-hospital complications related to the index admission at index admission for IVL L6 procedure (baseline)

All secondary outcomes will be ascertained using routinely collected clinical data from medical records and standard
follow-up, in keeping with the non-interventional, observational nature of the study

Completion date
01/12/2034

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. A diagnosis of symptomatic peripheral arterial disease (PAD), meaning reduced blood flow to the legs causing symptoms such as pain when walking or more severe limb symptoms
3. PAD classified as Rutherford stages 3 to 5, indicating moderate-to-severe symptoms that require treatment
4. Presence of calcified narrowing or blockage of the arteries supplying the pelvis or lower part of the main body artery (femoral, iliac or aorto-iliac arteries), confirmed on routine clinical imaging
5. The patient has already been selected by their treating clinical team to undergo intravascular lithotripsy (IVL) as the primary treatment, as part of their normal NHS or hospital care, independent of the study

6. Treatment with IVL has taken place within routine clinical practice at a participating hospital site
7. The patient is willing and able to provide written informed consent to take part in the study, including consent for the use of their routine clinical data and follow-up information for research purposes

These criteria ensure that the study includes patients who would normally receive IVL L6 for calcified femoral, iliac or aortoiliac artery disease without altering clinical decision-making or standard care pathways.

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. Under 18 years of age
2. Asymptomatic peripheral arterial disease, or PAD, not meeting Rutherford stage 3–5, where treatment with intravascular lithotripsy (IVL) is not clinically indicated
3. No significant arterial calcification in the femoral, iliac or aortoiliac arteries, or where IVL is not considered appropriate by the treating clinical team
4. Patients who do not receive IVL l6 as the primary treatment strategy for the target femoral, iliac or aorto-iliac lesion.
5. Patients in whom an alternative revascularisation strategy is used instead
6. Inability to provide informed consent, including lack of capacity to consent and no appropriate consultee process available.
7. Withdrawal of consent at any time prior to or during the study
8. Patients who are unwilling or unable to participate in follow-up, including refusal of follow-up contact or inability to be contacted by telephone

These exclusion criteria ensure that the study population is limited to adults with symptomatic, calcified iliac or aorto-iliac peripheral arterial disease who are able to provide consent and are receiving IVL as part of routine clinical care.

Date of first enrolment
01/05/2026

Date of final enrolment

31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

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

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

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

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

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

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

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

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

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

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board
Priory House
Monks Walk
Chicksands Shefford
England
SG17 5TQ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham
England
NG3 6AA

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
Shockwave Medical

Alternative Name(s)
Shockwave, Shockwave Medical Inc

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	11/08/2026	17/08/2026	No	No