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Assessing the appropriate duration of treatment for patients diagnosed with a blood clot in the their left heart chamber

Submission date
25/11/2025

Recruitment status
Recruiting

Registration date
06/03/2026

Overall study status
Ongoing

Last Edited
30/03/2026

Condition category
Circulatory System

[ ] 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
Left ventricular thrombus (LVT) is a condition which occurs following a heart attack (Acute coronary syndrome). Following a heart attack event, the heart muscle is weakened and does not pump blood around the body as well as it needs to. In around 20-30% cases blood clots forms in the main chamber of the heart (left ventricle), because the blood is more stagnant than usual. If all (or fragments) of this clot break-off and becomes lodged in other organs, it has serious consequences, such as stroke, or even death.
To prevent this, blood-thinning medication (anti-coagulation) are prescribed to dissolve the clot. Despite this around 40% of these clots remain after treatment. Most of these clots become firmly stuck to the heart muscle, and therefore don't move to other areas of the body. However, for some time, doctors have chosen to treat patients with persistent blood clots beyond the recommended 6- month period to reduce the risk of stroke. This is driven by consensus and not evidence. Moreover, bleeding is a well-recognised risk to continued anticoagulation treatment. Therefore, we propose a pilot randomised controlled trial (RCT) to explore the optimal treatment duration for Left ventricle thrombus (Clot).
The LVT Duration is a pilot study aimed to assess whether there is benefit to anticoagulation beyond the initial 3-6month period.

Who can participate?
Patients aged 18 years or older, with diagnosis of left ventricular (LV) thrombus within the past 12 months; receiving apixaban at the time of randomisation; completion of at least three months of anticoagulation treatment for LV thrombus; and either persistent laminar or mural thrombus, or persistent left ventricular dysfunction.

What does the study involve?
120 patients will be recruited from NHS hospitals and chosen at random to continue their blood thinning medication or not. They will then be followed up at 6 months with clinical evaluation and scans. The total duration of follow up will be 18months. The findings from this study will help us determine the practicalities of conducting a large RCT.

What are the possible benefits and risks of participating?
Benefits:
Taking part in this study may help us to understand the ideal duration of treatment for blood clot within the heart's main chamber. There may not be a direct benefit to your participation, but we hope the data will help inform management of blood clots in the future.
You will be closely monitored during this study and will have ready access to the research team if you should have any concerns or questions.

We have recognised the following risks:
1. Anticoagulation: The risk of continuing anticoagulation would involve bleeding, interaction with other medications and gastrointestinal effects. The risk of stopping anticoagulation could possibly be stroke and systemic embolisation due to thrombus dislodgement or new thrombus formation. These risks will be evaluated and monitored on an individual basis.
2. CMR: Overall MRI is a safe imaging modality compared to other forms of imaging. Potential risks are claustrophobia, tinnitus, movement of implantable devices, and the radiofrequency energy can cause heating leading to thermal injuries. The scans will be done by experienced radiographers and specialist cardiologists to minimise the hazards. Moreover, pre scan questionaries will be undertaken to make sure the patient can have a CMR without any adverse effects.
3. Transthoracic Echocardiography (TTE): TTE is a safe imaging modality compared to other imaging modalities. Potential risks are discomfort due to positioning or pressure from the transducer, allergic reaction if contrast is used, and minor skin irritation/ redness from the gel. The scans will be performed by experienced sonographers to minimise any potential ill effects.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
March 2026 to December 2027

Who is funding the study?
Barts Charity (UK)

Who is the main contact?
bartshealth.lvt@nhs.net

Contact information

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Public

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1008221

Study information

Scientific Title
A randomised pilot study assessing the optimal duration of anticoagulation for left ventricular thrombus

Acronym
LVT Duration

Study objectives
Primary objective:
To compare the composite outcome of Stroke and Systemic embolisation (SSE) and mortality with continuing versus stopping anticoagulation.
Secondary objectives:
1. To compare major bleeding (BARC ≥ 3) rates with continuing versus stopping anticoagulation.
2. To compare rates of minor bleeding (BARC ≤ 2) rates with continuing versus stopping

anticoagulation.
3. To compare the rates of new LV thrombus reoccurrence with continuing versus stopping anticoagulation.
4. To compare the rates of LV thrombus resolution with continuing versus stopping anticoagulation.
5. To compare the number of days in hospital with continuing versus stopping anticoagulation.
6. To compare rates of MI and target vessel revascularisation (TVR) with continuing versus stopping anticoagulation.
7. To compare the Quality of life (EQ-5D5L) of patients with continuing versus stopping anticoagulation.
8. To determine the perspectives of clinicians and patients with continuing versus stopping anticoagulation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/03/2026, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8089; cambridgecentral.rec@hra.nhs.uk), ref: 26/EE/0008

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)
Safety, Not Specified

Health condition(s) or problem(s) studied
Left ventricle thrombus based on aetiology- Acute Coronary Syndrome

Interventions
Patients with a diagnosis of left ventricular (LV) thrombus in the context of acute coronary syndrome (ACS) will be pre screened. As part of standard clinical care, all patients will already have undergone follow up imaging (CMR or TTE) after their initial diagnosis. Patients with either (a) persistent LV thrombus or (b) persistent LV systolic dysfunction despite thrombus resolution will be approached for participation.

Eligible participants will be randomised in a 1:1 ratio using a secure, web based randomisation system (REDCap). Randomisation will allocate participants to one of two open label trial arms:
Arm 1 – Continue Oral Anticoagulation (OAC): Participants will continue the oral anticoagulant therapy already initiated by their clinical team at the time of LV thrombus diagnosis. This may include apixaban, rivaroxaban, or warfarin. Dosing, frequency, and route of administration will follow standard clinical prescribing (oral administration; dose and frequency according to the licensed regimen for each agent). No changes to treatment will be introduced by the study.
Arm 2 – Stop Oral Anticoagulation: Participants will discontinue their oral anticoagulant therapy at the point of randomisation. Dual antiplatelet therapy (DAPT) may be re initiated if clinically indicated, according to standard care. No new investigational medicinal products will be introduced.
The study does not initiate or modify any medication beyond the randomised continuation or cessation of existing OAC therapy. All anticoagulants used in the study are open label and prescribed as part of routine clinical management.
Follow up: At baseline, data collection will include clinically acquired imaging results (CMR or TTE), routine blood tests, and quality of life assessments. At 6 months post randomisation, participants will undergo repeat imaging (CMR or TTE), routine blood tests, quality of life assessments, and a review of clinical endpoints and adverse events.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
apixaban, rivaroxaban, warfarin

Primary outcome(s)
The composite outcome of systemic thromboembolism (SSE) and all cause mortality is measured using clinical event data obtained from hospital records and study follow up at baseline and at 6 months (±3 months) after randomisation.

Key secondary outcome(s))
1. Major bleeding events (BARC ≥ 3) are measured using clinical event reporting and hospital records at baseline and at 6 months (±3 months) after randomisation.
2. Minor bleeding events (BARC ≤ 2) are measured using clinical event reporting and hospital records at baseline and at 6 months (±3 months) after randomisation.
3. New left ventricular (LV) thrombus formation is measured using echocardiography or cardiac imaging at baseline and at 6 months (±3 months).
4. LV thrombus resolution is measured using echocardiography or cardiac imaging at baseline and at 6 months (±3 months).
5. Total number of days spent in hospital is measured using hospital admission records from randomisation to 6 months (±3 months).
6. Total healthcare costs are measured using resource use data and standard costing methods from randomisation to 6 months (±3 months).
7. Myocardial infarction (MI) and target vessel revascularisation (TVR) events are measured using hospital records and clinical follow up at baseline and at 6 months (±3 months).
8. Quality of life is measured using the EQ 5D 5L questionnaire at baseline and at 6 months (±3

months).
9. Clinician and patient perspectives on the study are measured using qualitative interviews or structured questionnaires conducted during the study period up to 6 months (±3 months).

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Diagnosis of LV thrombus less than 12 months ago
2. Ongoing oral anticoagulation treatment at time of randomisation
3. Completed at least 3 months of anticoagulation treatment for LV thrombus
4. Persistent laminar/ mural thrombus or persistent LV dysfunction

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any clinical condition requiring long term anticoagulation treatment as per investigator’s judgement.
2. SSE since LV thrombus diagnosis
3. Contraindication to continuing anticoagulation therapy
4. Non-ischaemic Cardiomyopathy
5. Age less than 18 years
6. Unable to consent

Date of first enrolment
01/03/2026

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
Cardiology Research Department, St Bartholomew’s Hospital, West Smithfield
London
England
EC1A 7BE

Study participating centre
Mid and South Essex NHS Hospitals Trust
Broomfield Hospital
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CM1 7ET

Study participating centre
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Study participating centre
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St. James's University Hospital
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Study participating centre
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Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type

Funder Name
Barts Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
De identified IPD (including baseline characteristics, outcome measures, adverse events) will be available upon reasonable request following publication of the main results. Access will be granted to researchers with an approved proposal, subject to a data sharing agreement outlining conditions of use, data security requirements, and restrictions on re identification. Data will be available for 10 years after publication. Supporting documents such as the study protocol and statistical analysis plan will also be accessible.

IPD sharing plan summary
Available on request