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Early aortic repair in patients needing endovascular/open surgery for type B aortic dissection (EARNEST)

Submission date
30/01/2025

Recruitment status
Not yet recruiting

Registration date
04/02/2025

Overall study status
Ongoing

Last Edited
04/02/2025

Condition category
Surgery

[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
Uncomplicated Type B Aortic Dissection (uTBAD) is a serious condition where the inner layer of the aorta tears, which can lead to long-term complications like aneurysms, aortic rupture, or further dissection. The standard treatment focuses on managing blood pressure, but some patients still face life-threatening issues over time. Thoracic Endovascular Aortic Repair (TEVAR) is a minimally invasive procedure that uses a stent to reinforce the aorta, potentially reducing these risks. The EARNEST trial aims to find out if early TEVAR, done within three months of the initial dissection, improves patient outcomes compared to standard medical management alone.

Who can participate?
Patients with uTBAD who are 10 days to 3 months post-hospital admission for the initial event can participate. Participants must be at least 18 years old, have a life expectancy of at least 2 years, and be discharged from high dependency or critical care. They must also be off opiate painkillers or sedatives for at least 48 hours before enrolling and willing to provide written informed consent.

What does the study involve?
This is a randomised controlled trial, meaning participants are randomly assigned to one of two groups by a computer. One group will receive a stent (TEVAR), while the other will receive standard care. All participants will receive standard UK care, including blood pressure monitoring and medication as needed. Those in the stented group will have the procedure between 10 days and 3 months after dissection. Follow-up visits will occur at 6 weeks, 6 months, and annually, with health assessments and questionnaires. Regular CT or MRI scans will monitor the aorta and any stents.

What are the possible benefits and risks of participating?
Participating in this trial may offer potential benefits, such as better overall outcomes from early TEVAR, though this cannot be guaranteed. The study aims to improve treatment for all patients with dissection in the future. Participants will have regular health check-ups and imaging, and any incidental findings will be reported to their GP.

Risks include procedural risks from TEVAR, such as bleeding, artery narrowing, wound infections, heart attack, pneumonia, blood clots, and reduced blood supply leading to stroke or other issues. Serious complications are rare, but they can occur. Both CT scans and TEVAR use ionising radiation, which carries a very small increased lifetime cancer risk.

Where is the study run from?
The study is run from Imperial College London (UK).

When is the study starting and how long is it expected to run for?
September 2024 to February 2034.

Who is funding the study?
NIHR HTA Programme (UK)

Who is the main contact?
Please contact the EARNEST study team at earnest@imperial.ac.uk.

Study website
https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/earnest-study/

Contact information

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Scientific, Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327350

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 66215

Study information

Scientific Title
Early Aortic Repair in patients Needing Endovascular/open Surgery for Type B Aortic Dissection (EARNEST): A randomised trial to assess the clinical and cost-effectiveness of thoracic endovascular aortic repair in the subacute phase after uncomplicated type B aortic dissection.

Acronym
EARNEST

Study objectives
To determine whether early TEVAR in addition to BMT and surveillance compared to BMT and surveillance decreases the composite outcome of aortic-related mortality, severe permanent neurological deficit, or severe permanent cardiorespiratory failure over five years.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 11/12/2024, Solihull Research Ethics Committee (Equinox House, City Link, East Midlands REC Centre, Birmingham, NG2 4LA, United Kingdom; +44 207 1048191; solihull.rec@hra.nhs.uk), ref: 327350/1701896/37/526

Study design
Parallel arm multicenter open label superiority randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Participant information sheet
https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/earnest-study/

Health condition(s) or problem(s) studied
Uncomplicated type B aortic dissection

Interventions
Study Design and Randomisation
EARNEST is a multicentre, open-label, superiority randomised controlled trial (RCT) designed to assess the effectiveness of early intervention with Thoracic Endovascular Aortic Repair (TEVAR) combined with Best Medical Therapy (BMT) and Surveillance (SURV) compared to BMT and SURV alone in patients with uncomplicated Type B Aortic Dissection (uTBAD). Participants are allocated in a 1:1 ratio to one of the two study arms using a minimisation algorithm, which ensures balance across key prognostic factors (centre, age, and sex). Randomisation is conducted using a validated web-based system, Sealed Envelope.
Blinding is not possible due to the nature of the intervention; however, endpoint adjudication will be carried out by an independent expert panel

• Study Arms
1. TEVAR + BMT + SURV Group (Intervention Arm)
• Treatment: Participants undergo Thoracic Endovascular Aortic Repair (TEVAR) within 3 months of the index uTBAD event. TEVAR is performed at 25 specialist vascular centres across the UK.
• Follow-up Duration: Minimum of 5 years post-enrolment.
• Surveillance & Assessments:
o CT/MRI at 6 weeks , 12 months, 1, 2, 3, 4, 5 years
o Follow-ups at 6 weeks, 6 months, 1 year, and annually up to 5 years.

2. BMT + SURV Group (Control Arm)
• Treatment: Participants receive Best Medical Therapy (BMT) and clinical surveillance without TEVAR, unless clinically indicated per existing guidelines.
• Follow-up Duration: Minimum of 5 years post-enrolment.
• Surveillance & Assessments:
o CT/MRI at 6 weeks , 12 months, 1, 2, 3, 4, 5 years
o Follow-ups at 6 weeks, 6 months, 1 year, and annually up to 5 years.
o Late TEVAR intervention is permitted only if clinically necessary.

Randomisation Process
• 470 participants will be randomised 1:1 using a minimisation algorithm with a random component.
• The algorithm is stratified by age, sex, and centre to ensure balance across the study arms.
• Randomisation is conducted via a web-based system (Sealed Envelope).

Intervention Type
Procedure/Surgery

Primary outcome measure
Time to first of aortic-related mortality AND/OR severe permanent neurological deficit AND/OR severe permanent cardiorespiratory failure measured using patient records throughout follow up from randomisation until the first composite event. Patients censored if there is a competing event (non-aortic-related death, patient withdrawal or end of the study). Reported when all patients are five years after randomisation

Secondary outcome measures
1. Aortic-related mortality is measured using patient records at one year for the TEVAR group and five years after randomisation for all patients
2. All-cause mortality is measured using patient records at one year for the TEVAR group and five years after randomisation for all patients
3. Complications including stroke, paraplegia, and cardiorespiratory failure are measured using patient records throughout follow up and reported at one year for the TEVAR group and five years after randomisation for all patients
4. Reinterventions are measured using patient records throughout follow up and reported at one and five years after randomisation
5. Quality of Life (QoL) is measured using EQ-5D-5L questionnaires at baseline, 6 weeks, 6 months, 12 months, and then annually from randomisation until the end of follow up
6. Aortic remodelling is measured using CT/MRI scans assessed using a specific CT analysis protocol from the core lab at one year after TEVAR in the intervention group and at five years
7. Costs are measured using health resource use and cost data at 6 weeks, 6 months, 12 months, and then annually from randomisation and analysed at 5 years
8. Cost-effectiveness is measured using health resource use and cost data at 6 weeks, 6 months, 12 months, and then annually from randomisation and analysed at 5 years
9. Controlled blood pressure is measured using blood pressure recordings at baseline, 6 weeks, 6 months, 12 months, and then annually from randomisation until the end of follow up and analysed at 5 years

Overall study start date
01/09/2024

Completion date
01/02/2034

Eligibility

Key inclusion criteria
1. Patients with uTBAD, 10 days-3 months after the day of admission with acute uTBAD to hospital (the date of the index event)
2. Age ≥18 years
3. Life expectancy ≥2 years

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
470

Key exclusion criteria
1. Complicated TBAD (ruptured aorta, aortic dilatation >5cm or visceral/limb/spinal malperfusion, persistent pain or uncontrolled BP).
2. Previous TBAD.
3. Type A dissection
4. At significant risk from complications (either from condition related to the dissection or not – rephrase) during TEVAR

Date of first enrolment
01/09/2025

Date of final enrolment
01/09/2029

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

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

Study participating centre
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
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Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

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

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Barts and the London NHS Trust
Alexandra House
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Cambridge University Hospitals NHS Foundation Trust - Oxford Covid19 Trials
Nihr Cambridge Clinical Research
Cambridge Biomedical Campus
Hills Road
Cambridge
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CB2 0QQ

Study participating centre
The Guys and St Thomas' NHS Trust
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London
United Kingdom
SE1 9RT

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

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

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
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L7 8XP

Study participating centre
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Oxford Road
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M13 9WL

Study participating centre
Basildon and Thurrock University Hospitals NHS Foundation Trust
Basildon Hospital
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SS16 5NL

Study participating centre
Norwich
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NR4 7UY

Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor type
University/education

Website
https://www.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will aim to present the findings from the study to the Vascular Society, British Society of Endovascular Therapy, American Heart Association and the European Society of Vascular Surgery. We will aim to publish the findings of the trial in widely disseminated high impact academic journals.

Intention to publish date
01/02/2034

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication