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A study testing a new heart scan method to improve pacemaker treatment for heart failure

Submission date
15/07/2025

Recruitment status
Recruiting

Registration date
28/08/2025

Overall study status
Ongoing

Last Edited
01/09/2025

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
Cardiac resynchronization therapy (CRT) is a device treatment for patients with heart failure which cannot be managed by medications alone. CRT can help the heart contract more efficiently and improve the pumping function. However, many patients do not benefit from this treatment. Therefore, a better selection tool will help us to determine the most suitable patients to receive this treatment. A new measure of pumping function of the heart called: first-phase ejection fraction or EF1 has been shown a good tool to select suitable patients for CRT. EF1 is a sensitive measurement of heart function and can be easily measured by echocardiography (an ultrasound heart scan).
The purpose of this study is to examine whether this new measurement (EF1) can predict outcomes and response to CRT treatment.

Who can participate?
Patient age over 18 years, on optimal medical therapy for heart failure and fulfilling standard consensuses guidelines for CRT.

What does the study involve?
Patients s will have their usual care, with extra measurements from heart scans to see how they predict response to CRT. They will have follow-ups at 6, 12, and 36 months, and if no improvement is seen at 6 months, device settings may be adjusted and checked again 6 months later.

What are the possible benefits and risks of participating?
Whilst there may not be direct benefit to you by taking part, the study findings may benefit future patients with similar conditions. Taking part in this study is very unlikely to cause you harm. The EF1-guided CRT optimisation method uses the same non-invasive heart scan (echocardiogram) already used in your routine care. Adjusting the timing settings of your CRT device is a standard part of treatment, and EF1-guided optimisation is simply a new way to help choose the best settings.

Where is the study run from?
The trial will take place at 4 centres in the UK. The main centre is Guy's & St Thomas' NHS

Foundation Trust in London and will be coordinated from King’s College London Clinical Trials Unit.

When is the study starting and how long is it expected to run for?
Recruitment began in August 2025 and will continue until the August of 2027. Follow-up will be for a minimum of 36 months, and the study is expected to finish in July2030.

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

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

IRAS number
353637

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 69668

Study information

Scientific Title

Evaluation of first-phase ejection fraction to guide cardiac resynchronisation therapy-a randomised controlled trial

Acronym
EFFECT-CRT

Study objectives
The purpose of the present application is:
1. To verify in a multi-centre prospective study that EF1 is sufficiently robustly predictive of CRT response so as to be useful in guiding the selection of patients for CRT
2. To investigate whether EF1 could be used as a target against which CRT parameters can be optimised in a multi-centre RCT
3. To examine the relationship between global and regional early systolic function to understand how response to CRT relates to these
measures

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 09/07/2025, London Westminster Research Ethics Committee (The Old Chapel Royal, Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8066; westminster.rec@hra.nhs.uk), ref: 25/LO/0562

Study design
Multicenter interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiac resynchronisation therapy, heart failure

Interventions
People with heart failure who are referred for a special pacemaker treatment called cardiac resynchronisation therapy (CRT) will be invited to take part. Everyone will have their usual heart assessments, including heart scans, blood tests and routine check-ups, before and after the pacemaker is fitted.

Six months after their CRT implant, the doctors will check how well their heart has responded. If the heart has not improved as expected, participants will be randomly allocated (using a secure online system) into one of two groups:
Standard Care Group: The pacemaker settings will be adjusted in the usual way, based on standard heart scan measurements that look at how well the heart fills with blood.
EF1-Guided Group: The pacemaker settings will be adjusted using a new heart scan measurement called EF1, which looks at how strongly the heart pumps at the very start of each heartbeat.
After these adjustments, all participants will continue with their usual care and have follow-up visits at 12 months and again at 36 months to see if their heart function and symptoms have improved.

Intervention Type
Other

Primary outcome measure
Volumetric response measured as a reduction in left ventricular end-systolic volume >15% using echocardiography at 6 months after CRT implantation.
Clinical improvement measured using the Clinical Composite Score (CCS) at 6 months after CRT implantation

Secondary outcome measures
Hospitalisation for heart failure or death (clinical events reviewed from patient medical records and telephone call) at 36 months after CRT implantation

Overall study start date
09/07/2025

Completion date
31/07/2030

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Strong understanding of English
3. On optimal medical therapy for heart failure
4. Fulfilling standard consensuses guidelines (NYHA class II-IV, EF ≤35% and QRS duration>130ms) for CRT (including conduction pacing system)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
400

Key exclusion criteria
1. Co-morbidity expected to reduce life expectancy to less than 6 months
2. Major cardiovascular event in the previous 6 weeks
3. More than mild aortic stenosis
4. Continuous or intermittent infusion therapy for heart failure
5. Suboptimal ultrasound acoustic window
6. Inability to give informed consent
7. Current participant in other interventional studies

Date of first enrolment
01/08/2025

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St. Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Kings College Hospital
Mapother House

De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

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

Publication and dissemination plan
We plan to publish the trial results in a high-impact peer-reviewed journal and present the results at an international cardiology conference.
We also plan to disseminate the results to the trial participants, recruiting hospitals, relevant PPI groups, and the relevant local, national, and international clinical and regulatory bodies.

Intention to publish date
31/07/2031

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

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