

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

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<b>Registration date</b> 28/08/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/09/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 consensus guidelines for CRT.

### What does the study involve?

Patients 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 July 2030.

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?

Haotian Gu, Haotian.gu@kcl.ac.uk

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

### Integrated Research Application System (IRAS)

353637

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)**

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

## **Key secondary outcome(s)**

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

## **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 consensus guidelines (NYHA class II-IV, EF  $\leq$ 35% and QRS duration >130ms) for CRT ( including conduction pacing system)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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**

United Kingdom

England

**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

Beckett Street

Leeds

United Kingdom

LS9 7TF

# Sponsor information

## Organisation

King's College London

## 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

## 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