

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

Submission date 15/07/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/08/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/09/2025	Condition category 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

Dr Haotian Gu

ORCID ID

<https://orcid.org/0000-0003-3270-4347>

Contact details

King's College London
Clinical Research Facility
St Thomas' Hospital
London
United Kingdom
SE1 7EH
+44(0)2071884700
haotian.gu@kcl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)

353637

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