

CROSS sectional versus invasive imaging in patients with Heart Failure

Submission date 22/08/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/09/2025	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

Each year in the UK at least 60,000 patients are diagnosed with heart failure. Coronary artery disease (narrowing of the blood vessels supplying the heart) is the most common cause of heart failure. It is important to identify coronary artery disease because these patients have an increased risk of dying and may respond less well to modern treatments. Invasive coronary angiography (described below) is often done as the first-line test to identify coronary artery disease in a fifth of patients with heart failure in the UK. However, it is known from work with our patient and public involvement groups and patient charities (including the British Society for Heart Failure Patient Group and Cardiomyopathy UK) that most patients would prefer to avoid invasive coronary angiography if possible. This trial aims to establish if it is possible to reduce the need for invasive angiography in patients with newly diagnosed heart failure.

Who can participate?

Patients presenting with a new diagnosis of heart failure and not known to have coronary artery disease

What does the study involve?

They will be randomly assigned (equal chance) to one of three tests:

1. Invasive coronary angiogram (current NHS practice)- A specialised X-ray test where dye is injected directly into the heart arteries via the groin or wrist. It carries a small risk of serious complications such as stroke. The test exposes patients to radiation and is expensive (NHS tariff up to £1563). Furthermore, there are long waiting lists for the test following many cancellations due to the COVID-19 pandemic.
2. CT coronary angiography - this test is quick, non-invasive and cheaper than invasive angiography (NHS tariff up to £310). It has a high accuracy for the detection of coronary artery disease but can be challenging in certain patient groups such as elderly patients or those with irregular heart rhythms. It also exposes patients to a small dose of ionising radiation.
3. Stress cardiovascular MRI - This test is non-invasive and cheaper than invasive angiography (NHS tariff up to £596) and provides additional information on the structure and function of the heart. The accuracy of this test for detection of coronary artery disease is unproven in patients with heart failure. It does not expose patients to ionising radiation.

The recruitment strategy aims to maximize the inclusion of patients who have been underrepresented in heart failure trials, such as elderly individuals, ethnic minorities, and socio-economically disadvantaged patients. Efforts will be made to reduce barriers to participation, and collaboration with the NIHR Ethnic Minority Research Inclusivity Group will help create a YouTube video explaining the trial's rationale and the importance of participation. The video will be presented in plain language and made available in multiple languages.

The trial is designed to minimize inconvenience for patients by eliminating the need for additional hospital visits. Follow-up will be conducted remotely, primarily through the review of electronic health records. Surveys exploring patient experiences will be sent via online platforms, text messages, or post, based on patient preference. The trial will also assess whether the tests provide good value for money for the NHS.

If the trial shows that non-invasive imaging tests are as effective as invasive angiography, it could lead to a significant reduction in the number of angiographies performed annually in the NHS. This could result in improved patient experience and cost savings without compromising the health outcomes of patients with heart failure.

What are the possible benefits and risks of participating?

Although direct benefits to participants cannot be guaranteed, the information gained might help the treatment of future patients. Participants will have more contact with medical staff and have more opportunities to ask questions and be informed about their health. All tests in this trial are standard NHS care so there are no additional research tests or additional risks to participating in the study. There is however a small burden of patient time to complete the consent form and questionnaires at baseline, 6 months and 12 months. To minimise inconvenience, questionnaires will be offered in a variety of formats including telephone, postal and online.

Where is the study run from?

University of Leeds (UK)

When is the study starting and how long is it expected to run for?

April 2024 to August 2029

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)

Scientific, Principal investigator

Contact name

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Type(s)

Public

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Integrated Research Application System (IRAS)

332073

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

2024-NCT25, CPMS 57653

Study information**Scientific Title**

CROSS sectional versus invasive imaging in patients with Heart Failure

Acronym

CROSS-HF

Study objectives

To establish whether, in patients with heart failure, a strategy of non-invasive imaging with computed tomography coronary angiography (CTCA) or stress cardiovascular magnetic resonance (CMR) is non-inferior to invasive coronary angiography (ICA) in terms of major adverse cardiovascular events (MACE), patient reported outcome measures, and cost-effectiveness.

Ethics approval required

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Ethics approval(s)

approved 14/08/2024, West of Scotland REC (Ground Floor Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 24/WS/0108

Study design

Multicentre open-label randomized controlled trial

Primary study design

Interventional

Study type(s)

Diagnostic, Quality of life

Health condition(s) or problem(s) studied

Heart failure

Interventions

Participants will be randomised (online) 1:1:1 ratio to either invasive coronary angiogram (ICA), non-invasive imaging with computed tomography coronary angiography (CTCA) or stress cardiovascular magnetic resonance (CMR). Each test is expected to take between 1 h 20 minutes and 1 h 45 minutes. Participants will be asked to complete up to 3 questionnaires at baseline, 6 months and 12 months but completion of each questionnaire is expected to take no more than 20 minutes. Follow-up by review of medical records at NHS sites will be up to 4.5 years and longer-term follow-up through remote data linkage for up to 10 years.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Time to first major adverse cardiovascular event (MACE) measured from randomisation for a minimum of 12 months:

MACE defined as any of:

1. All cause death
2. Myocardial Infarction (MI)
3. Heart Failure Hospitalisation

Key secondary outcome(s)

Measured using patient records:

1. Total MACE events (MACE is defined as all-cause mortality, MI and heart failure hospitalisations)
2. Total (first and recurrent) HF hospitalisations
3. KCCQ-CSS at 6 and 12 months
4. Total Cardiovascular (CV) deaths
5. Total all-cause mortality

Completion date

01/08/2029

Eligibility

Key inclusion criteria

1. Onset of symptoms ± signs of heart failure in the past 12 months AND
- 2.1. Non-elective heart failure hospitalisation (where heart failure was the primary reason for hospitalisation in the opinion of the investigator) OR
- 2.2. Outpatients with LVEF $\leq 40\%$ OR
- 2.3. Outpatients with LVEF $> 40\%$ and NT-proBNP $> 300\text{ng/L}$ (sinus rhythm) or $> 600\text{ng/L}$ (AF)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Previous investigations for coronary artery disease (CAD), where CAD was identified as the cause of heart failure
2. Clear alternative cause of heart failure (e.g. cardiac amyloidosis or hypertrophic cardiomyopathy)
3. Severe valvular heart disease thought to be the main cause of heart failure
4. Comorbid conditions with lifespan of less than a year (in the opinion of the investigator)

Date of first enrolment

01/10/2024

Date of final enrolment

01/04/2028

Locations

Countries of recruitment

United Kingdom

England

Scotland

Wales

Study participating centre

Leeds Teaching Hospitals NHS Trust

St. James's University Hospital

Beckett Street

Leeds

United Kingdom

LS9 7TF

Study participating centre

Pinderfields Hospitals NHS Trust

Trust Hq, Rowan House

Pinderfields General Hospital

Aberford Road

Wakefield

United Kingdom

WF1 4EE

Study participating centre

NHS Greater Glasgow and Clyde

J B Russell House

Gartnavel Royal Hospital

1055 Great Western Road Glasgow

Glasgow

United Kingdom

G12 0XH

Study participating centre

Northumbria Healthcare NHS Foundation Trust

North Tyneside General Hospital

Rake Lane

North Shields

United Kingdom

NE29 8NH

Study participating centre

Kettering General Hospital NHS Foundation Trust

Rothwell Road

Kettering

United Kingdom

NN16 8UZ

Study participating centre

Bradford Teaching Hospitals NHS Foundation Trust

Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre

James Paget University Hospitals NHS Foundation Trust

Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre

The Royal Wolverhampton NHS Trust

New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre

Airedale NHS Foundation Trust

Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

Study participating centre

Norfolk and Norwich University Hospitals NHS Foundation Trust

Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre**Barnsley Hospital NHS Foundation Trust**

Gawber Road
Barnsley
United Kingdom
S75 2EP

Study participating centre**Glenfield Hospital NHS Trust**

Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information**Organisation**

University of Leeds

ROR

<https://ror.org/024mrx33>

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

Not provided at time of registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	01/08/2024	06/09/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes