CROSS sectional versus invasive imaging in patients with Heart Failure (CROSS-HF)

STUDY SUMMARY SHEET

- You are invited to take part in a research study comparing different ways of investigating patients who have heart failure.

- Heart failure is a condition where your heart can't pump blood around your body as well as it should. It doesn't mean your heart has stopped working but you may need tests to better understand why this has happened.

- All tests done in this study are standard NHS care. The study is simply investigating which is the best test for individual patients. Each test has their own individual risks and benefits.

- The study is funded by the National Institute for Health Research, which is the major government funder of research in the UK.

- If you consent to take part in the study you will be randomly assigned to one of three groups:

Group 1	**CT coronary angiogram**
Group 2	**Stress magnetic resonance imaging (MRI)**
Group 3	**Invasive coronary angiogram**

- The test you have will be reported in the normal way at your hospital and your management will not be altered by participating in this study.

- There are no extra hospital visits.

- Members of the research team will need access to your records during and after study participation. We will only use information that we need for the research study and everyone involved in this study will keep your data safe and secure, following strict privacy rules.

- You will not benefit directly from taking part in the study.

- You do not have to take part if you do not want to, in which case you would receive standard care instead.

The research team will also be happy to explain the study in more detail to you in person.

CROSS-HF

CROSS sectional versus invasive imaging in patients with Heart Failure

Chief Investigator: Dr Peter Swoboda, University of Leeds
Local Principal Investigator: <*insert name and hospital details*>

PATIENT INFORMATION LEAFLET

Dear Patient,
You are being invited to take part in a research study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why have I been chosen?
This study is looking at people like you, who are being treated for heart failure. Heart failure is a condition where your heart can't pump blood around your body as well as it should. It doesn't mean your heart has stopped working but you may need tests to better understand why this has happened. We will be asking 3000 people, in several UK hospitals, to take part in this study.

Purpose of the study
There are several tests available to help us find out if heart failure is caused by narrowing of the heart arteries (coronary heart disease). We are trying to establish the best test patients should have first. We hope to find the test strategy that gets each patient to their correct diagnosis as safely as possible.

Do I have to take part?
No. It is up to you to decide whether to take part. Taking part in medical research in the UK is entirely voluntary and you should feel under no pressure to take part if you do not think it is right for you. A member of the study team will discuss the study with you and what it involves. If you do decide to take part you will be given this information leaflet to keep and be asked to sign a consent form.

You are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care that you receive from the NHS.

What will happen to me if I take part?
Coronary artery disease is the most common cause of heart failure. There are currently three tests available which are all routinely performed in the NHS to identify if heart failure is caused by coronary artery disease:

- CT coronary angiogram
- Stress MRI
- Invasive coronary angiogram

If you agree to participate in the study you will be randomly allocated to which test you undergo. Neither you nor your doctor can influence what group you will be in. All heart tests in this study are commonly performed as part of routine NHS care. How the test is done is not being altered for this research study, it is simply trying to decide the best test to do first.

1. CT coronary angiogram: (1000 out of the 3000 patients will be in this group). If you are allocated to this group you will have a **CT coronary angiogram**. CT stands for 'computerised tomography' and is a sophisticated type of X-ray. You will lie on a bed inside a scanner and will be asked to hold your breath briefly for the scan to be performed. During the **CT coronary angiogram** you will receive an injection of a contrast dye into a vein in your am. You may also receive an injection of a medicine (a beta-blocker) to slow your heart rate down a little bit. This can help reduce the time you will need to hold your breath for.

What happens next: The CT scan will be reported by a consultant who is an expert in this area in your local hospital. Depending on the result your further treatment will be decided by your own cardiologist.

2. Stress MRI: (1000 out of the 3000 patients will be in this group). If you are allocated to this group you will have a stress MRI. MRI stands for magnetic resonance imaging and does not use radiation (unlike the other tests in this study). **Stress MRI** takes approximately 40 minutes to complete. You lie in a short 'tunnel', which holds a large magnet. There are no known risks from the technique although some people may experience claustrophobia. You may receive a sedative to help you tolerate the scan. Short bursts of magnetic fields and radio waves from the MRI scanner allow images to be created. During the scan, you will have an injection of MRI contrast medication. You will also have an injection of medication (Adenosine), which is a drug to increase the blood flow to your heart. This medication is used routinely in many heart tests.

What happens next: The stress MRI scan will be reported by a consultant who is an expert in this area in your local hospital. Depending on the result your further treatment will be decided by your own cardiologist.

3. Invasive coronary angiogram: (1000 out of the 3000 patients will be in this group). An angiogram is a heart test that looks at the blood supply of your heart. It is possible to see narrowings inside heart arteries and is the most commonly performed test to look for heart artery disease. Serious complications are rare and affect less than one in 1000 patients but include things such as damage to the blood vessel where the catheter was inserted, heart attack or even stroke.

A special dye is injected into an artery in your arm or leg, which travels to your coronary arteries. When it gets there, an x-ray photograph is taken of the artery to look for any narrowings of the coronary arteries. This may be a sign of coronary heart disease.

- You'll be given a local anaesthetic injection in the wrist or groin, which numbs the area. The doctor will make a small cut and the catheter (a thin, flexible tube) will then be pushed into an artery.
- A special dye called contrast will then be passed through the catheter and a series of images will be taken. The dye will show up any narrowed areas or blockages in the artery on the X-ray photos.
- You will be awake and able to talk to the medical team throughout your procedure.
- If you are feeling very anxious about having this test, you can ask for a mild sedative to help you relax.
- As long as you feel well, you should be able to go home the same day.

What happens next: Your invasive coronary angiogram will be reported by a consultant who is an expert in this area in your local hospital. Depending on the result your further treatment will be decided by your own cardiologist.

Health Questionnaires:If you agree to participate in this part of the study, you will be invited to complete simple health questionnaires when you join the study, after six months, twelve months and then annually until the end of the study. This can all be done online, by telephone or post and should take no longer than 20 minutes each time.

Baseline data collection: With your permission personal data will be collected from your hospital records including your demographics, medical history, cardiac medications, clinical assessments and results from recent blood tests, ECGs and echocardiograms.

Follow–up: No extra hospital visits are required. As part of the study we would like to keep track of your health. We will try to do all of this by review of your NHS records but occasionally we may need telephone you. If needed this phone call would be once a year at most. With your permission we will also look at your hospital records, request access to your GP records, central NHS records and/or use information from NHS central records for up to 10 years after study completion.

It is very helpful if we can continue to track your health over the long term. NHS Digital allows us to access health information about you with your permission. In order to this we are seeking your permission to provide NHS Digital with some of your personal details (including your name, date of birth, address and NHS or CHI number) and with this information they will be able to provide us with simple health information about you for a period of up to 10 years. It is very important to understand the long term health condition of patients to find out if the treatments we are giving are effective. Information will be provided to NHS Digital in strict confidence and will be kept securely and will not be released to a third party.

What are the possible disadvantages and risks of taking part?
All of the tests in this study are routine care within the NHS and you will not undergo any additional research procedures.

Both CT coronary angiogram and invasive coronary angiogram use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure although the doses used in modern tests are very low. Because there are standard tests the chances of this happening to you are the same whether you take part in this study or not.

Benefits to you
We cannot promise the study will directly benefit you, but the information we get from this study might help the treatment of future patients. If you take part in the study you will have more contact with us, and have more opportunities to ask questions and be informed about your health, which some patients find helpful.

Expenses
You will not be asked to undergo any extra tests or hospital visits as a result of taking part in this study, so you will incur no extra expenses.

Will my taking part be kept confidential?
All information collected about you during the study will be kept strictly confidential. This information will be held securely and anonymously in electronic format on the Leeds and Glasgow Universities' secure servers, and on paper, under the provisions of the 2018 Data Protection Act. We will also keep electronic copies of your scan images with all of your identifiable data removed. The data collected will be coded and your personal details (Name, NHS/CHI Identifier, date of birth and address) will be kept in a separate secure database to permit longer term record linkage for 10 years after the study has finished. Individual participating NHS hospitals/Trusts, on behalf of the University of Leeds (sponsor), will keep identifiable information about you and your contact details for the purpose of the study for 20 years after the study has finished.

We may contact the NHS Digital or other central NHS UK bodies at a later stage for information which they hold on your health status. This means some of your personal data will be shared with NHS Digital. Any information exchanged between us and NHS Digital will be subject to strict data protection laws.

With your permission, your data may also provide a resource for future studies. If any information from this study is used to develop new research, data protection laws will be observed and strict confidentiality maintained. Any information about you which leaves the hospital will have your name and address removed so that you cannot be identified. Your data and or images may be sent to institutions/ commercial organisations in the UK, the European Economic Area or outside the EEA. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. Ethical approval will be obtained for any future studies involving your data. With your consent we may also wish to contact you in the future

about new studies you may wish to participate in. We will never give your personal details to any researchers outside of our department.

If you withdraw consent from further study follow-up, or if you were to become incapacitated, any data collected about you up to that point will remain on file and will be included in the final study analysis. If you wish to withdraw from completing the trial questionnaires you will be asked if you still consent to have follow up through review of electronic records.
For more information on the use of your personal data for clinical research please refer to the following sources:
University Privacy notice: https://ris.leeds.ac.uk/privacy-notice/
University DPO: dpo@leeds.ac.uk
HRA information on patient data use in research: https://www.hra.nhs.uk/information-about-patients/

What will happen to the results of the research study?
When the study is complete the results will be published in a medical journal, but no individual patients will be identified. If you would like a copy of the published results, please ask your doctor.

Indemnity/Compensation
The University, when acting as Sponsor, has insurance cover in force, which meets claims against it and where those claims arise from the Universities own negligence in its role and activities relating to the study (and which is subject to the terms, conditions and exceptions of the relevant policy). Clinical negligence indemnification will rest with the participating NHS Trust under standard NHS arrangements.

Complaints
If you have cause to complain please contact the research team in the first instance or for independent complaints, please contact the Sponsor Representative at The University of Leeds on governance-ethics@leeds.ac.uk.

The research organisation
This is a research project of the Leeds Institute for Cardiovascular and Metabolic Medicine at the University of Leeds and the *<insert local hospital name>*, in collaboration with the Glasgow Clinical Trials Unit (GCTU). It is being funded by National Institute for Health and Care Research (NIHR). The University of Leeds is acting as sponsor for the study.

Who has reviewed the study?
The study has been reviewed and approved both by the <*insert details when known*> Research Ethics Committee and by your local NHS Research and Development Office. More details can be provided, on request, by your study doctor.

For further information please contact:
1) <*insert local hospital lead research nurse name, email and telephone*>
2) <*insert local hospital principal investigator name, email and telephone*>

There is also a Participant Information Video available at <Insert hyperlink when available>.

If you would like independent general advice about participating in clinical research, please discuss this with your Clinical Care Team.

Thank you for taking time to read this information leaflet.

NIHR | National Institute for Health Research

UNIVERSITY OF LEEDS

CROSS-HF

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CI: Dr Peter Swoboda

Site PI: *<insert name and hospital details>*

CONSENT FORM

Patient Study Number: …….. Patient Initials.....

	Please Initial Each Box
I have read the Patient Information Sheet dated 1st August 2024 (version 1.1) for the above study and I have had the opportunity to ask questions and discuss the research study and I am satisfied with the answers to my questions.	
I understand that my participation is voluntary, and I am free to withdraw from the study at any time without giving a reason.	
I understand that data and images collected in this study will be stored on computer systems at Leeds and Glasgow Universities, after my personal details have been removed..	
I understand that anonymised data and images may be shared with researchers at participating organisations and also with researchers at other institutions/ commercial organisations in the UK, the EEA, and countries outside the EEA (e.g. USA).	
I understand that relevant sections of my medical notes and data collected during the study (including personal data) may be looked at by individuals from the University of Leeds and Glasgow Clinical Trials Unit (GCTU), from regulatory authorities, or by the local research team, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that information held by the NHS, by my General Practitioner, and information held and managed by NHS England and Public Health Scotland may be used to provide information about my health status. I give permission for this information to be obtained from NHS England and Public Health Scotland, the NHS Central Register and/or my GP if necessary. To do this, I understand that my details (including my name, address, NHS number, CHI number and date of birth) will be shared by Universities of Leeds and Glasgow with NHS England and Public Health Scotland where relevant to this study for up to 10 years and for clinical and personal data to be stored for up to 20 years after study completion.	
If I were to lose capacity or withdraw consent for further follow-up, I understand that data and images already collected will be kept and used for the purposes of the study.	
I agree to take part in this research study and that the general results of the study will be made available to the medical community most likely through publication in a reputable medical journal.	

I agree to completing self-assessed quality of life questionnaires.	
I am willing to be contacted again in the future with regard to potentially taking part (without any obligation) in further related research studies (optional)	

Signature.....

Name (block capitals)..... Date.....

Signature of researcher.....

Name (block capitals).....Date.....

Original copy to be retained by the researcher
1 copy for the patient
1 copy to be filed in the medical records (paper notes or electronic version)