Detecting EARLY heart failure in Greater Manchester (EARLY-HF)

Participant information sheet

You are being invited to take part in a research study being carried out by Manchester University NHS Foundation Trust. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. 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.

What is the purpose of the study?

Heart failure is a disease in which the heart is unable to pump blood around the body effectively. As people age, heart failure becomes increasingly common, and it is a major cause of death and disability in middle-aged and older people. Currently, heart failure is usually diagnosed too late, after people have already developed severe symptoms or need to come to hospital. It is important to identify people with heart failure much earlier in the hope that we can start treatments earlier and prevent progression to more severe disease.

We have developed a method that provides an indication of a person developing heart failure or becoming unwell with it. It currently includes measurements of heart structure and function made from cardiac MRI scanning, blood levels of a marker of fluid retention and medical history factors.

This study aims to evaluate this in people living in Greater Manchester. We hope that many people will take part in the study. We are particularly keen to include people from ethnic minorities and people registered at GP practices serving more deprived areas of the City.

Why have I been asked to take part?

You have been invited to take part because you are aged 50 or over, and you have one or more of the following conditions: type 2 diabetes, chronic obstructive pulmonary disease (COPD), coronary heart disease, atrial fibrillation, high blood pressure (even if treated), kidney impairment, body mass index ≥ 30 kg/m2.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be asked to sign a consent form. If you decide to take part and then change your mind you are free to withdraw

at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will in no way affect the standard of care you receive now or in the future.

What will happen to me if I decide to take part?

If you agree to participate, you will be invited to the British Heart Foundation Manchester Centre for Heart and Lung Magnetic Resonance Research (MCMR) at Wythenshawe Hospital for a research appointment. In total, this appointment will last approximately 60 minutes.

- You will be asked to sign a study consent form.
- You will be asked about any heart related symptoms you may be experiencing and have your height, weight and blood pressure measured.
- You will have a heart trace (ECG) to measure the electrical activity of the heart
- You will have a blood sample of up to up to 30 ml taken.
- You will undergo an MRI scan of your heart. The scan will last approximately 20 minutes. The scan will involve you lying in the scanner on a padded bed. You will be asked to hold your breath at times while some of the images are taken. Prior to the scan a small plastic tube will be inserted into a vein in your arm and image 'dye' (gadolinium-based contrast agent) will be given through the cannula during the scan.

You will not be required to attend any follow-up research appointments. We may occasionally contact you by phone in relation to this study for the duration of the study, if required.

On the study consent form, you will be asked to agree to the collection of information relevant to your past and future health from medical, health, social care and other health-related records, which are collected or held in local, regional and national systems. The information collected may include: general practice (GP) records, hospital records, national health-related data collected by national organisations (such as NHS Digital, the Office for National Statistics, Public Health Scotland, Research Data Scotland, the SAIL Databank for Wales), national or local audit data, or any other source of information relevant to your health. Information that may be collected includes, but is not limited to: medical history, diagnoses, symptoms, signs, prescriptions, medications, vaccinations, referrals to various health professionals, laboratory tests (for example, on your blood and urine), scans (for example, imaging scans of your heart, brain and body), information on hospital attendances and admissions, death registry information, lifestyle, and any other health-related information. Only information related to cardiovascular disease, its associations and complications will be collected. This information will be collected for up to 5 years following your participation in the study and will be held securely on a database at Manchester University NHS Foundation Trust (MFT). Only current or future members of the research team who need this information to undertake the research will have access to this information. This information will be linked to a pseudo-identifier

code (as explained in the sections below), so people who do not need to know who you are will not be able to see your name or contact details.

What are the benefits of taking part?

There may be no direct benefit for you. You will only be informed of unexpected abnormalities (for example a previously unrecognised heart attack), and with your consent, we will inform your GP. You will not be routinely informed of the results of the blood tests, ECG or cardiac MRI scan. You will not be informed of your individual risk score of developing heart failure because we do not yet know how accurate this is.

Patients who take part in research may have a better understanding of their condition by spending more time with the research team and having the opportunity to ask questions. By taking part you will help to improve our understanding of early heart failure and support the development of new diagnostic tests and treatments.

What are the possible disadvantages and risks of taking part?

Blood sampling and the cannula insertion may involve some short lived discomfort and can lead to a bruise.

Cardiac MRI scanning is considered to be very safe. It uses magnetic fields to produce the images. It does not use harmful radiation. There are no known risks associated with MRI scanning. The NHS website describes MRI scanning as “a painless and safe procedure” and “one of the safest medical procedures available” (https://www.nhs.uk/conditions/mri-scan/). As the scanner uses a magnetic field, some people who have implanted metal devices, such as a pacemaker, will not be able to have a scan. The scan can be quite noisy, but you will be provided with earplugs and headphones to wear. Some people may experience claustrophobia. Our MRI staff will do all that they can to make you feel comfortable during the scan, and will be monitoring you via a video camera. You will be able to talk with the radiographer at any time during the scan. If we are unable to make you feel comfortable in the scanner, we will not go ahead with scanning. Your scan is being performed for research purposes and therefore is not a diagnostic scan as would be performed clinically. However, if an unexpected abnormality is found on the scan, with your consent, we will inform your GP.

The image ‘dye’ (gadolinium-based contrast agent) is used routinely in clinical practice, and given to many thousands of patients in the UK every year. As with any injection, reactions may rarely occur. These may include a warm sensation at the injection site, nausea or vomiting and transient skin rash. These effects usually only last for a few minutes. People with a history of allergy are more likely to suffer a more severe reaction, but this is very rare (less than 1 in 3,000 people). The department is equipped to cope with allergic reactions if they happen.

Will I receive payment for taking part?

You will not be paid for taking part, but we will reimburse any reasonable travel costs for attending the research appointment.

How will we use information about you?

We will need to use information from you and your medical records for this research project.
This information will include the following:

- Initials
- NHS number
- Name
- Contact details
- Medical History including test results
- Cardiac MRI scan images
- Blood samples

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number (pseudo-identifier) instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

How will you look after and use my blood sample?

Your sample will undergo initial processing and storage at Manchester University NHS Foundation Trust.

In order to take part in this study, you will need to agree for your blood sample to be tested for a wide variety of laboratory analyses (including genetic testing), and for your blood samples to be used as part of this study or for use in future research. These will help us to improve the risk calculator and improve our understanding of early heart failure.

Blood samples for future research will be used in study areas related to cardiovascular disease, its associations and complications.

Sample analyses may include analyses of your genes as well as of proteins, lipids, carbohydrates and a wide range of other analyses. The analysis of your genes may include determining the

sequence of part or all of your DNA code. Your sample, and the information generated from the analyses of it, will be linked to all of your other information collected as part of the study.

Your sample will be labelled with a pseudo-identifier, which is a unique code assigned to your participation but that does not reveal your identity. This is called “pseudonymised”. The analyses will be done on pseudonymised samples. No personal details that might identify you will be kept with the sample or passed to external teams carrying out sample analyses.

Will my information and sample be shared?

Your pseudonymised study information, including genetic information, may be shared for research purposes with researchers or organisations, including commercial companies, in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America, where data protection laws may differ. The sponsor is taking appropriate safeguards to make sure your personal information is protected.

Analyses of your pseudonymised sample, including genetic analyses, will be carried out by the most suitable team. This may be within facilities run by the NHS, research organisations or commercial companies. The facilities may be based in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America.

Requests for access to data and samples will be managed by the study sponsor. Release of data or samples to researchers or organisations requesting access will be covered by specific agreements. The agreements are legally binding, and will regulate the use of data and samples, and ensure that standards are maintained.

The results of analyses of study information and samples will be presented in reports, publications and presentations. You will not be identified personally in any of these. At the end of the study, information held in the research database may be transferred to research or scientific archives for use in scientific and medical research. Lay summaries of the study findings will be posted to the trial website www.earlyhf.org.

What are my choices about how my information and sample are used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we will ask you to choose one of the options set out in the next section. We need to manage your records in specific ways for the research to be reliable, which means that we will not be able to let you see or change the data we hold about you.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

- At https://research.cmft.nhs.uk/getting-involved/gdpr-and-research
- By asking one of the EARLY-HF Score research team
- By contacting the Sponsor's Data Protection Officer (dpo@mft.nhs.uk)

What if I no longer want to be a part of the study?

You can stop being part of the study at any time, without giving a reason. If you choose to stop taking part in the study, please contact the research team. The contact details are given at the end of this information sheet. We will ask you to choose one of the following options:

1. No further contact with you. We will stop further contact with you. However, you allow research using your information and sample to continue, and you allow continued collection of information from your medical, health, social care and other health-related records, which are collected or held in local, regional and national systems.

2. No further contact with you and no further analysis of your sample. We will stop further contact with you. Any remaining sample from you that has not already been used for analysis will be destroyed so it cannot be used in new analyses. However, you allow research to continue using information already held about you, including from previous analysis of your sample, and you allow continued collection of information from your medical, health, social care and other health-related records, which are collected or held in local, regional and national systems.

3. No further contact with you and no further research using your samples or information. We will stop further contact with you. Any remaining sample from you that has not already been used for analysis will be destroyed so it cannot be used in new analyses. We will stop collecting information from your medical, health, social care and other health-related records. No further research will be conducted using the information we hold about you.

If you choose to stop taking part in the study but it is not possible to confirm your preference, Option 1 will be implemented. For all options:

- Your personal information will be retained in an archive so that a record remains of your initial study consent and the withdrawal process.
- We will keep information about you that we already have. Existing data cannot be destroyed. Data that has been securely distributed, analysed or used in reports or publications cannot be reversed or withdrawn.
- If you choose options 1 or 2 you also agree that your existing data can continue to be used for future analysis. If you choose option 3, existing data will not be used for future analysis.
- It will not be possible to destroy sample already prepared, distributed for analysis, or analysed.

Who is running the study?

This study is being sponsored by Manchester University NHS Foundation Trust (MFT) and funded by Greater Manchester Innovation Accelerator and Astra Zeneca. The pharmaceutical company Astra Zeneca is providing financial support for the study. Astra Zeneca have not been involved in the design of this study. The release of data and samples to Astra Zeneca will be covered by separate legally binding agreements as described previously in the section 'Will my information and sample be shared?'. Research publications arising from this study will be sent to Astra Zeneca for information only prior to submitting for publication in a medical journal.

All research in the NHS is approved by the Health Research Authority (HRA) and reviewed by an independent group of people called a Research Ethics Committee (REC). The Research Ethics Committee is made up of experts, non-experts and members of the general public. Together they review research applications to ensure your safety, rights, wellbeing and dignity are protected at all times.

This study has been reviewed and given favourable opinion by an NHS Research Ethics Committee and Health Research Authority.

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the lead researchers who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Patient and Liaison Service (PALS) or equivalent: email pals@mft.nhs.uk or telephone 0161 276 8686

The hospital is insured to carry out clinical research through the NHS Indemnity scheme, however the normal National Health Service complaints procedures should be available to you. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Manchester University NHS Foundation Trust but you may have to pay your legal costs.

Who do I contact for further information?

If you have any questions about the study, please talk with a member of the research team

Principal Investigator:
Professor Chris Miller
Chris.miller@mft.nhs.uk

Primary contact:
Dr Nicholas Black
Nicholas.black@mft.nhs.uk

We would like to thank you for taking the time to read this information sheet and potentially participating in the study.

Detecting EARLY Heart Failure in Greater Manchester (EARLY-HF)

CONSENT FORM

Participant Study Number:	H	F																		
Participant Surname:																				
Participant First name:																				
Participant DOB:			/			/														

To be completed by the participant

Once you have read and understood the information in each section, please enter your initials in each box. At the end of the form, print, date and sign your name.

1. **Taking Part (You must agree to all statements to take part)**
   a. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.
   b. I understand that participation is voluntary and that I am free to withdraw from the study at any time, without giving a reason, and without my care being affected. If I withdraw, I understand that I will be asked to choose one of the options explained in the information sheet.
   c. I agree to take part in this research study.

Initial here to confirm you have read and understand this section	

2. **Data (You must agree to all statements to take part)**
   a. I agree that the study team may collect information relevant to my past and future health from medical, health, social care and other health-related records, which are collected or held in local, regional and national systems. The information collected may include: GP records, hospital records, national health-related data collected by national organisations (such as NHS Digital, the Office for National Statistics, Public Health Scotland, Research Data Scotland, the SAIL Databank for Wales), national or local audit data, or any other source of information relevant to my health.
   b. I understand that national organisations, such as NHS Digital, may over time change their name or status. For the avoidance of doubt, I agree to any medical, health or social care-related information held via these types of organisations to be accessed, collected, and used as part of this study.
   c. I agree for the long-term storage and usage of my data, including in the event of my incapacity or death.
   d. I understand that my data will be held using a unique code (pseudonymised). All my data may be linked together, including my samples and information obtained from my samples, and analysed.
   e. I agree that my personal and contact details, such as my name, full date of birth, NHS number, address and contact details, and details of my GP, can be stored securely as part of this study, as described in the information sheet, and used for the purposes set out in the information sheet.
   f. I agree that my pseudonymised study data may be shared for research purposes with researchers or organisations, including commercial companies, in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America.
   g. I agree that information produced by analysing my data, including analysis of my samples, may be included in reports, publications or presentations. At the end of the study, I agree that my study data may be transferred to research or scientific archives for use in scientific and medical research. This data will be non-identifiable.
   h. I agree that a copy of this consent form may be uploaded to the study database.

Initial here to confirm you have read and understand this section	

3. **Blood sample (You must agree to all statements to take part)**
   a. I agree to give a blood sample of up to approximately 30ml.
   b. I understand that I am donating my blood sample and information about me as a gift.
   c. I understand that my sample will be labelled with a unique code (pseudonymised).

d. I agree for the long-term storage and use of my sample, including in the event of my incapacity or death.
e. I agree to my sample being analysed as outlined in the information sheet. This may include determining the sequence of part or all of my DNA (genetic) code.
f. I understand that my sample, and the information generated from my sample, will be linked to all of the other information collected as part of the study.
g. I understand that analysis of my pseudonymised samples may take place within NHS facilities, research facilities or by commercial companies, and may take place in the United Kingdom or overseas, including outside of the European Economic Area and in the United States of America.
h. I agree that my pseudonymised sample may be used in future research without my further permission.

Initial here to confirm you have read and understand this section	

4. Results (You must agree to all statements to take part)

a. I understand that the study team will not feedback any results obtained from my participation in the study to me.
b. I understand that the scan and blood tests are being performed for research purposes and therefore are not diagnostic, but if an unexpected abnormality is found, I give permission for my GP to be informed.

Initial here to confirm you have read and understand this section	

5. Other studies (Optional)

I understand that I may be invited to participate in other research studies based on data held or accessed about me, and/or analysis of samples I have donated. I will be provided with full information about these studies, when and if I am contacted. I understand that I am free to decide whether or not to take part in these studies.

Initial here to confirm you have read and understand this section	

By signing this form, you understand that you are agreeing to all of the sections above

Your first name and surname (BLOCK CAPITALS)			
Your signature		Date	

To be completed by the person taking consent			
First name and surname (BLOCK CAPITALS)			
Signature		Date	

Please file the original copy of this form in the site file (electronic or paper-based). Copies should be provided to the participant, included in the participant's health record and uploaded to the study database