Participant Information Sheet

NON-INVASIVE CORONARY THROMBUS IMAGING TO DEFINE THE CAUSE OF ACUTE MYOCARDIAL INFARCTION

You are invited to take part in a research study. To help you decide whether or not to take part, 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. Talk to others about the study if you wish. Contact 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 attacks are unfortunately very common and it is estimated that approximately 10,000 people in Scotland have a heart attack each year. We now have very sensitive blood tests that can pick up damage to the heart and find patients who have had a heart attack. However, whilst this is welcome, it does not identify what causes the heart attack and can sometimes pick up other conditions that cause a strain on the heart. The classic cause of a heart attack is when a blood clot forms on fatty deposits within the heart arteries. This leads to treating patients with blood thinning medication, and this is very effective and saves lives. However, many apparent heart attacks are not caused by blood clots and some may be caused by bloods but pass unrecognised.

In this study, we will test an exciting new imaging test that can 'see' from outside the body whether there is a blood clot in the heart arteries. This could provide a major new way of assessing patients to ensure they get the right diagnosis and the right treatment. This could ultimately improve the outcomes of our patients with heart attacks.

Why have I been invited to take part?

You have been invited to take part as you have recently been diagnosed with a heart attack. We are looking for 80 people with a recent heart attack for the study.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

If you agree to take part, you will be invited to discuss the details of the study with a member of the research team who will make sure you understand everything. You will then be asked to sign a consent form. We will review your clinical records including medical history, ECG, heart x-ray pictures, and blood tests to confirm your eligibility for the study. We will also ask you some questions about your health. If you are either pregnant or breastfeeding, you will be unable to

take part in this study. You may be asked to take a pregnancy test if the possibility of pregnancy cannot be excluded.

The research study involves participants undertaking the following research procedures and assessments:

1. A combined Positron Emission Tomography and Computed Tomography (PET-CT) scan of your heart
2. Ultrasound scan of your heart
3. MRI scan of your heart
4. An electrical tracing of your heart (ECG)
5. An examination of the heart including heart rate and blood pressure measurements
6. A blood test - a total of up to four tablespoons (60 mL) of blood will be taken for immediate testing and the remaining blood will be stored for future ethically approved studies
7. A follow up questionnaire 6 -12 months following your heart attack

Table 1. Overview of Research Procedures

Research Procedure	Time taken to complete procedure	Time from diagnosis of heart attack to procedure
Examination, blood test and ECG	40 minutes	1-7days
Ultrasound of heart	30 minutes	1-7 days
PET-CT scan of heart	100 minutes	1-7 days
MRI heart scan (if required)	60 minutes	1-7 days
Follow up Questionnaire	10 minutes	6- 12 months

PET-CT scan

If you are eligible to take part, you will be asked to undergo a PET-CT scan as soon as possible. This scan uses X rays and involves radiation to take pictures of your heart and heart blood vessels.

Figure 1. PET CT scanner

You will be accompanied to the imaging facility where the scan will take place. You will be asked to change into a hospital gown. A plastic tube (cannula) will be placed into your arm and you will receive an injection of a radioactive tracer called ^{18}F-GP1. This radiotracer is a chemical that binds to blood clots and releases radioactive signals that are picked up by our specialised scanner. Through this, we can identify where the blood clots are within the body. ^{18}F-GP1 has been used successfully in various patient research studies to explore clotting in the lungs, legs, blood vessels, heart and in devices. You will then be asked to lie quietly for 60 minutes whilst the tracer circulates around the body. You will then be brought through to the PET-CT scanner.

The scanner is simply a large circular shaped machine that is open at both ends with a sliding table, pictured above. You will be asked to lie on a flat scanning table. You can speak with the doctors and radiographers throughout the entire scan. If you need to speak to the doctor or radiographer during the scan, you will be able to attract attention by pushing the patient buzzer. They will then speak to you over the intercom or come into the scanner room to speak to you.

During the scan, you will receive an injection of a contrast 'dye' through the small plastic tube in your arm.

The time that you will be within the PET-CT scanner will be 40 minutes. This is in addition to the 60 minutes needed for the tracer to circulate your body before the you enter the scanner.

Your travel expenses will be reimbursed on provision of a valid receipt.

MRI heart scan

For some patients in our study, it will be necessary to have an additional MRI scan of your heart as well as the CT-PET scan as part of your standard NHS care. The MRI scanner is a large circular tunnel shaped machine that is open at both ends with a sliding table. In the scanning room, you will be asked to lie down on your back on the scanning bed for up to 1 hour. The radiographers will ensure that you are as comfortable as possible. A blanket can be provided if you are feeling cold.

During scanning, you will be asked to stay as still as possible. If you need to speak to the doctor or radiographer during the scan, you will be able to attract attention by pushing the patient buzzer. They will then speak to you over the intercom or come into the scanner room to speak to you.

There is no radiation with this type of scan and you don't need to take any precautions after this scan.

Some people cannot have MRI head scans. This includes people with certain metal implants or claustrophobia. A trained member of the study team will go through the check list with you to ensure you are eligible to have a MRI head scan.

Heart ultrasound (ECHO) and electrocardiogram (ECG)

What is an echocardiogram?

An echocardiogram or 'echo' is a scan that uses ultrasound (sound waves) to produce pictures of the heart. The test is painless and without side effects. It does not use radioactivity. We are

performing this in order to see if there is any evidence of clot within the heart chambers, heart valves or whether there is small hole between the heart chambers. What does it involve?

This will be performed in the Clinical Research Facility in the Royal Infirmary of Edinburgh or you will have already had one on the ward by the clinical team. You will be taken into a room with low level lighting. The person performing the test is called a sonographer, who may be male or female. The sonographer will usually not be a doctor. A clinical research doctor will also be present during the scan.

You will be asked to undress to the waist, gowns are available that should be left open to the front. You will be asked to lie on a couch on your left-hand side. If you require a chaperone, you may bring a friend or relative. Alternatively, the hospital may provide a chaperone at your request.

Stickers will be attached to your chest and connected to the machine. These will be used to monitor your heart rate during the test.

An ultrasound probe covered by a small amount of gel is placed gently on the chest and the sonographer will record a number of pictures of the heart.

The test will take approximately 30-40 minutes to complete. There is no preparation needed for this test.

Following your echocardiogram, a 12-lead ECG will be performed. We will attach stickers to your chest, arms and legs, and take an electrical tracing of her heart rhythm. You are likely to have one of these tests during your time in hospital. It takes approximately 5 minutes and is painless with no radiation exposure.

For some patients your medical team will already have arranged for an echocardiogram to be done. If this is the case only one test will be performed either by the research team for this study or by the routine cardiology department.

Follow Up Questionnaire

Between 6 and 12 months following your tests, we would like you to complete a questionnaire about your medical conditions and medications that you are taking at that time. This will be emailed or posted to you with a prepaid envelope to return to us. We will contact you once by telephone if the questionnaire has not been completed or if we need to clarify some details. At this time, we will also review your electronic medical notes. There will be no further follow up after the questionnaire. We will keep your anonymised data which may be used in further ethically approved studies.

Is there anything I need to do or avoid?

After the PET-CT scan, you will still have small amounts circulating radiation. We therefore ask you to avoid travelling home by public transport and restrict physical closeness with others for at least 6 hours. This is particularly important to remember around pregnant women and children.

What are the possible benefits of taking part?

You may benefit from the extra tests and closer follow up during the conduct of the research. By participation in clinical research, you may also provide benefit to other people who have had heart attacks or are at risk of having a heart attack in the future. For aiding us with our research and attending for assessment, your travel expenses will be reimbursed on provision of a valid receipt up to a value of £100.

What are the possible disadvantages of taking part?

If you take part in this study, you will have one PET-CT scan including a CT scan of the heart. This exposure is additional to those that you would have if you did not take part in the study. The scan uses ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to 50% of people at some point in their life. Taking part in this study increases the chances of this happening to you from 50% to 50.2%.

After your PET injection you will be slightly radioactive for a few hours, and you may be asked to avoid close contact with potentially pregnant women and children for a few hours following your PET scan.

In order for us to inject the radiotracer, a plastic tube (cannula) will be inserted into the blood vessel (vein) in your arm using a needle. There is a small risk of bleeding, bruising and infection from the cannula being inserted. Using this tube, we will also be able to inject a contrast dye into your bloodstream (to make the images of your heart vessels visible) during the scan. The most important potential risk is an allergic reaction to the contrast dye which is very rare (serious allergic reactions occur in approximately 1 in 10,000 patients) and we have clear procedures for managing such reactions. The contrast dye is generally very safe in patients with normal kidneys. In patients with kidney disease, it can impair their kidney function further. For this reason, patients with significant kidney disease will not be able to participate in the study.

Taking part in the research study does require you to give up your own time to do so. Where possible, we will ensure research procedures are carried during the same visits to reduce the number of visits required. We also will ensure procedures and assessment are carried out in timely manner and at your convenience.

What if there are any problems?

If you have a concern about any aspect of this study, please contact Dr Craig Balmforth (details below) who will do their best to answer your questions.

In the unlikely event that something goes 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 your local NHS Organisation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

As part of the study, we will obtain images of your heart. After your scan(s), a doctor will examine the images and there is a small possibility that unexpected or unrelated problems may be found. On rare occasions, an abnormality may be found which requires further investigation or treatment. If we detect something wrong in your scan(s) or the other tests we perform, we will contact you and your GP and arrange further tests as necessary. Although a significant problem is unlikely, you should be aware that if such a problem is detected, then this may have consequences for your treatment. Some serious incidental findings, although rare, may also have implications for your insurance and job or finances, and so this should also be considered

What will happen if I don't want to carry on with the study?

If you decide to take part in the study, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. If you decide to stop being in the study, we will ask you to inform Dr Craig Balmforth. You can find his contact details at the end of this leaflet.

In the unlikely event that you lose the capacity to consent to medical research during the study, the research team would not collect any more of your details and you would be withdrawn from the study. Information that has already been collected will be retained and used in the study.

What happens when the study is finished?

At the end of the research, we will analyse the data collected, which will be anonymised. There is no follow up required from the study and your usual medical care will not change as part of the study. If you agree, anonymised data, blood samples and in some cases tissue, samples may be used for future ethically approved studies. You will not be identifiable in these data.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical record for this research project. This information will include your initials, name, age, sex, height, weight, CHI number, address, postcode, telephone number, email address and consent form. A CHI number is a code unique to every person in Scotland that allows identification of paper and electronic health records. This data will be kept on a password protected NHS computer and will not leave the NHS IT system.

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 study number instead. We will keep all information about you safe and securePhysical documents containing personal data will be kept to a minimum and stored in locked files accessible only to members of the research team. Paper files will be kept in a locked cabinet in the Centre for Cardiovascular Sciences, Chancellors Building,

Royal Infirmary of Edinburgh. Electronic data will be stored on a secure password encrypted database in Microsoft Excel on University of Edinburgh computers within the Centre for Cardiovascular Science. All data will be anonymised before transfer to the University computers. Any information held on computers will be securely stored and access granted to the research team only. The data will be anonymised before it is analysed to protect your confidentiality. Some anonymised blood samples may be sent to other academic institutions or commercial companies for analysis. With your consent, we will inform your GP that you are taking part in this study.

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.

What are your choices about how your information is 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 would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to craig.balmforth@ed.ac.uk
- by ringing us on 07730097889

What will happen to the results of the study?

The results of this study will be written up as an academic research project and will be submitted for publication within a medical journal. It is possible that the results may also be presented at academic meetings or conferences. You will not be identifiable in any published results. If you would like a summary of the results of the study, this may be

provided via telephone or appointment. This can be arranged by contacting Dr Craig Balmforth (contact details are at the end of the information sheet) and you will be provided with the website address on which the study is published.

Who is organising and funding the research?

This study has been sponsored by the University of Edinburgh and NHS Lothian. Additionally, this study forms part of a PhD research project funded by

Who has reviewed the study?

The study proposal has been reviewed by a wide range of members of the research team. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). A favourable ethical opinion has been obtained from the REC. NHS management approval has also been obtained.

Researcher Contact Details

If you have any further questions about the study please contact Dr Craig Balmforth on: 07730097889 or email on: craig.balmforth@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contac

Dr Rong Bing, Consultant Cardiologist
rong.bing@nhslothian.scot.nhs.uk

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk
0131 536 3370

Participant ID:

CONSENT FORM
NON-INVASIVE CORONARY THROMBUS IMAGING TO DEFINE THE CAUSE OF ACUTE MYOCARDIAL INFARCTION

	Please **initial** box
1. I confirm that I have read and understand the information sheet for the above study. ***Date (DD MMM YYYY)** | ***Version Number** | | **complete during consent process*	☐
2. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected.	☐
4. I give permission for the research team to access my medical records for the purposes of this research study.	☐
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records.	☐
6. I give permission for my personal information (including initials, name, age, address, postcode, telephone number, email address and consent form) to be to be passed to the Clinical Research Centre (Royal Infirmary of Edinburgh) for administration of the study.	☐
7. I give permission for my Community Health Index (CHI) number or hospital number to be collected and retained on NHS servers	☐
8. I agree to my General Practitioner being informed of my participation in the study and agree to their providing health information to the research team if necessary	☐
9. I agree to my personal data being held for 12 months to 3 years and imaging data for at least 5 years.	☐
10. I agree to have a venous blood sample taken and analysed as part of this study but also to be stored and used for future ethically approved studies.	☐
11. I agree to undergo the research study procedures.	☐
12. I understand that my anonymised blood samples may be sent to other academic institutions or commercial companies for analysis and that I will not benefit financially from any commercial use to which my samples may be put.	☐
13. I agree to my anonymised data being used for future ethically approved studies.	☐

Participant ID:

CONSENT FORM
NON-INVASIVE CORONARY THROMBUS IMAGING TO DEFINE THE CAUSE OF ACUTE MYOCARDIAL INFARCTION

	Please **initial** box
14. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further ethically approved studies.	☐
15.I agree to take part in the above study.	☐

Name of Person Giving Consent	Date	Signature
Name of Person Receiving Consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record