

Participant Information Sheet

Clinical Patients – With Contrast and/or Stressing Agent: 3T

Study Title: Protocol Optimisation for Advanced MRI Research Studies

You are being asked to take part in a clinical research study. Before you decide it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the information sheet carefully and discuss it with others if you wish. Please ask us if there is anything you are unclear about or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

Many different research studies are carried out in the Magnetic Resonance Imaging (MRI) units at the Queen Elizabeth University Hospital (involving the heart, liver, kidneys, limbs etc.), which we hope will help to improve the service that the NHS provides to patients in the coming years. However before we start a new study, we need to know that the MRI scans that we do will provide the best possible images and information for the studies. The purpose of this study is to allow us to try out the scans that we would like to use in other research studies on a small number of people first to make sure that they are as good as possible (“optimised”) before the larger studies begin.

Why have I been invited to take part?

You have been invited to take part because you are already involved in an MRI research study in which you will be given contrast and/or a stressing agent, or because you responded to a recruitment poster or were approached in a clinic by a doctor who is involved in research, and you have a health problem which is relevant to another study which we would like to carry out. Your involvement will allow us to make sure that the quality of MRI scans are as good as possible before the actual study begins.

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 asked to sign a consent form, and given a copy to take home. If you decide to take part you are still 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 not affect the standard of current or future care you receive.

What will happen to me if I take part?

When you come for your scan, we will discuss the study with you and if you want to take part you will be asked to sign a consent form. A member of the research team will also take you through a pre-scan checklist to make sure that it is safe for you to enter the scanner. A copy of the checklist is attached at the end of this document, and

we would ask you to read through it and contact Tracey Hopkins 0141 201 2455 before your scan if you answer “yes” to any of the questions, or if you have any concerns. Once you have been approved to enter the scanner you will be asked to change into a gown and taken into the MRI room.

Once in the MRI room, you will be positioned on the table and an object called a coil, which obtains the images, will be placed on the area of your body which we would like to scan. The table will then move into the scanner, and the scan will begin.

You will be given earplugs or headphones to reduce the noise generated by the machine to an acceptable level. Some participants may find the process of an MRI scan potentially claustrophobic however you will be monitored throughout and will be able to communicate with the research team via intercom should you wish to stop at any time.

During your scan, we would like to give an injection of an MRI contrast agent (gadolinium), which is a type of dye that allows us to see certain parts of the body more clearly, into a vein in your arm. As with any injection, there is a risk that you may have a reaction to the contrast agent. However, this risk is extremely small, and in the unlikely event that you do experience a reaction, then a doctor will be present to assist you.

Some types of heart MRI scans are used to assess your heart when it is working harder than usual, for example when you are exercising. It is not possible for you to exercise while inside the scanner, so we can make your heart work harder by giving you a medicine called Adenosine, which will be injected into a vein in your arm. Adenosine will make your heart beat faster and you may experience a feeling of heaviness in your chest. This will only last for 3 – 4 minutes, and then any symptoms will quickly pass. In the unlikely event that you feel unwell during or after the injection of Adenosine, then a doctor will be present to assist you. If you are having a scan which involves Adenosine, then it is important that you **do not drink or eat anything containing caffeine** (coffee, tea, caffeinated soft drinks, chocolate) for **24 hours** before your scan.

If you are already taking part in an MRI research study, then the “optimisation” scans will increase the scan time stated in your other Participant Information Sheet by a maximum of 15 minutes.

In some cases we may ask you to attend for further scanning and repeat the MRI scan to check if the new technique gives the same results each time.

If the repeat scan is to be done on the same day we will bring you out of the scanner for a break and refreshment. Any effects that you experience from being in the scanner e.g. dizziness will pass once you are removed from the scanner. When you are ready we will repeat the scan. It is likely that you will feel the same effects when you go back in for repeat scanning. The total time for this will not exceed 2 hours of scanning time. Or we may ask that we book the repeat scan for another day which suits you.

You do not have attend for any repeat scanning if you do not wish and may change your mind at any time, even after a first or second scan, and pull out of the study.

We would only request further imaging if you are already taken part in an MRI Research study where the optimisation scans have already been added. This will either be specified in the protocol or you will be offered the opportunity to specifically consent to a repeat scan being undertaken.

The specific details of the scan which we would like you to have are provided at the end of this document.

Do I need to do anything before the scan?

There is no preparation required on your part before having the scan. As mentioned previously, if you are having a scan which involves Adenosine, then it is important that you **do not drink or eat anything containing caffeine** (coffee, tea, caffeinated soft drinks, chocolate) for **24 hours** before your scan

What are the risks involved in participating?

There may be certain implants or devices in or on your body which may mean that will not be allowed to take part in this study. This is because the scanner is a powerful magnet and uses radiowaves. You will be taken through a safety checklist prior to entering the scanner room to determine if it is safe for you to participate. It is very important that you answer the safety checklist honestly and that you seek clarification for anything which you do not understand. The safety checklist will be treated confidentially.

What are the benefits in my participation?

You may not receive any direct benefit from the scan, but the information that we get may improve the quality and amount of information that can be obtained from scans in subsequent clinical trials, and hence help to improve treatment of patients in the future.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. All images collected from the scans will be anonymised before any analysis is carried out on them, therefore you will not be able to be identified from the images in any way. Your personal information will be kept on file and stored in a secure place at the Imaging Centre of Excellence, Queen Elizabeth University Hospital.

However because we are working in partnership with the scanner manufacturer to develop protocols your imaging data will be visible to them on the scanner i.e. your name and date of birth. However if we choose to share scans with them for analytical or marketing purposes, such scans will always be anonymised

How will the images from my scan be used?

Your images will help us to decide what we need to do to make sure that the scans we use in future research studies are as good as possible. We may also use your images to test analysis software. Your images may be used in scientific presentations and for teaching purposes, but no information will be used that would allow you to be identified.

Will my GP be informed?

We do not intend to routinely contact your GP, however you may choose to discuss your involvement with your GP yourself. A doctor involved with the study will look at all of your images, and in the unlikely event that an abnormal finding is detected, then we will contact you and will make arrangements for you to be referred to an appropriate specialist for further investigations. You should be aware that you may then have to disclose such findings in future applications for health-related insurance.

What will happen to the results?

You will not usually be informed of the results of your scan, unless it is necessary to refer you for further investigations. The results of the analysis will be used to improve our techniques for use in larger clinical studies initially, and hopefully to provide an improved service to patients in the future.

What if there is a problem?

This study is sponsored by NHS Greater Glasgow & Clyde. The sponsor will be liable for negligent harm caused by the design of the trial. NHS indemnity is provided under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). If you have any complaint about the way you have been dealt with during the study you should discuss this with the research team in the first instance. In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. The normal National Health Service complaints mechanism is also available to you and the contact telephone number for this is 0141 201 4500.

Who has reviewed the study?

The study has been reviewed and approved by the West of Scotland Research Ethics Committee 3 and NHS Greater Glasgow & Clyde Research and Development Department.

Thank you for taking the time to read this information sheet. If you have any questions or would like some more information, please feel free to contact a member of the research team and discuss it with them.

**For further information on the study,
please contact:**

Tracey Hopkins
Lead Research Radiographer
Queen Elisabeth University Hospital
Tel: 0141 201 2455
Email: tracey.hopkins1@nhs.net

**For independent advice on participating
in research, please contact:**

Dr Ruth Hamilton
Consultant Clinical Scientist
(Paediatric Physiological Measurement)
Royal Hospital for Children
Tel: 0141 452 4217
Email: ruth.hamilton@glasgow.ac.uk

PROTOCOL OPTIMISATION FOR ADVANCED MRI RESEARCH STUDIES

Details of 3T MRI Scan

Area of Body

- Heart
- Abdomen
- Limbs
- Head/Neck

Injection of Contrast?

- Yes No

Injection of Adenosine?*

- Yes No

Expected Total Time for Visit

Expected Time in Scanner

Further Information

Please see “Sample text for Further Information section of PIS” for examples. The text in this section will be reviewed by the CRIF Approval Group for each optimisation project

* If your scan involves an injection of Adenosine (“Yes”) then it is important that you **do not drink or eat anything containing caffeine** (coffee, tea, caffeinated soft drinks, chocolate) for **24 hours** before your scan.

** **Please Note:** Your research scan will take place in a facility which also scans emergency research patients. As a result, **your appointment time may be delayed or you may have to be removed from the scanner before your scan has finished, as priority must be given to emergency patients.** If this is the case then you will be given the option to wait or to rebook your appointment.



Clinical Research MRI Facility Screening Form
MR Controlled Access Area including Scanner Room



Assessed for 3T <small>Please vet</small>		Name: _____ Address: _____
Assessed for 7T <small>Please vet</small>		Date of Birth: _____ CHI: _____ Phone number: _____

Study name: _____	R&D number: _____	Investigator: _____
Study ID: _____	Weight: _____	Height: _____

<p>Have you ever:</p> <p>Had a cardiac pacemaker, implanted defibrillator or pacing wires? YES NO</p> <p>Had any surgery/procedure to your heart? YES NO</p> <p>▪ If yes, give details.....</p> <p>Had any surgery on your neck, head, brain or eyes? YES NO</p> <p>▪ If yes, give details.....</p> <p>Had any surgery involving the use of metal implants, plates, or clips? YES NO</p> <p>▪ If yes, give details.....</p> <p>Had any implanted, attached or ingested electronic, mechanical or magnetic devices? YES NO</p> <p>▪ If yes, give details.....</p> <p>Had any other surgery? YES NO</p> <p>▪ If yes, give details.....</p> <p>Had metallic injuries or metal fragments in your eyes /other parts of the body? YES NO</p> <p>Have metal dentures/dental plate, hearing aid or wig? YES NO</p> <p>Wear a limb, cast, crutch or brace? YES NO</p> <p>Have any tattoos, permanent makeup or body piercing? YES NO</p> <p>Wear any type of skin patch? YES NO</p> <p>▪ If yes, give details.....</p> <p>Contrast examinations – 3T only:</p> <p>Have any kidney problems, kidney failure or ever had dialysis? YES NO</p> <p>Have asthma, eczema, hayfever or any known allergies? YES NO</p> <p>▪ I will accept a contrast agent injection if required. YES NO</p> <p>Females:</p> <p>Could you be pregnant? YES NO</p> <p>▪ LMP date:</p> <p>▪ Have you been sterilised or have an IUD fitted? YES NO</p> <p>▪ Contrast examination: Are you breast feeding? YES NO</p>	
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Before entry into the examination room all metallic objects must be removed: Metal tools, scissors, keys, watches, papers, credit cards, coins, hair clips, hearing aid, jewellery and all other metallic items upon my person.

I have read and understood the contents of this form and confirm that the answers to the above safety questions are correct to the best of my knowledge. I have had the opportunity to ask questions about the MRI procedure that I am about to undergo.
Staff/participant/patient/visitor:

Name: _____ Signature: _____ Date: _____

Authorised Scanning Staff Member:

Name: _____ Signature: _____ Date: _____