**The James Cook University Hospital, South Tees NHS Trust**

**PARTICIPANT INFORMATION SHEET**

**The MINOCA CMR study**

Principal Investigators

Dr David Austin, Consultant Cardiologist, JCUH

Dr Adil Rajwani, Consultant Cardiologist, Royal Perth Hospital

***Invitation***

You are invited to participate in a research study because you have a condition known as ‘MINOCA’ - defined as a presumed heart attack without a blockage in the heart arteries. Before you decide whether to participate, it is important for you to understand why the study is being done and what it will involve. The following information sheet provides details about the study and aims to answer any questions you may have. Please take time to read the information carefully. Ask the study doctor or other research team member to explain anything that is not clear or if you would like more information.

***What is the purpose of the study?***

We would like to study whether advanced heart imaging called Cardiac Magnetic Resonance (CMR) - sometimes also called Cardiac MRI - helps us to better individualise treatment for patients presenting with MINOCA. This study will assess how information from a CMR changes your doctors’ diagnosis and treatment after MINOCA has occurred.

***What is MINOCA?***

A ‘typical’ heart attack results from an abrupt blockage or narrowing of a coronary artery by a blood clot, as a result of a build-up of fatty deposits in the artery. A coronary angiogram takes pictures of the heart arteries to identify a blockage or narrowing. In about one in ten cases there is no blockage or narrowing seen. In this situation, your doctor will not always be sure whether the blood clot has simply dissolved away (approximately 1 in 3 cases), or if in fact this was never a ‘typical’ heart attack and rather was another condition mimicking one. Examples of other conditions include viral infections causing inflammation of the heart muscle, spasm of the heart arteries or other heart disorders. Standard treatment for a heart attack includes a year of blood-thinning medications (antiplatelet therapy), even if the blood clot has resolved – this is very important in preventing recurrence of the heart attack. This is often what the doctor will choose to treat you with. However, in the 2/3rds of cases where the MINOCA was not actually due to a blood clot, patients will be receiving blood-thinners unnecessarily. Your doctor will make a considered assessment of the most likely cause, but a further test that helps to clarify the diagnosis could be very helpful.

***What research is being proposed?***

CMR obtains detailed pictures of the heart muscle and therefore could potentially be a very useful tool to identify an underlying cause of MINOCA. However, we don’t know how often the CMR actually changes the diagnosis, over and above the doctor’s clinical intuition. Consequently, we also don’t know if the information from the CMR is just of academic interest or if it genuinely helps to change treatment. Secondly, a CMR scan is expensive. On the other hand, it may be that stopping unnecessary medications actually saves far more money than the cost of the CMR. Stopping medications could also potentially reduce any complications from medicines. Finally, it is not clear whether there are certain subgroups of patients who are more or less likely to benefit from a CMR.

This research study will now help us to more clearly understand (i) how often a CMR will actually change a patient’s diagnosis; (ii) how often a CMR changes patient’s care; (iii) the value for money of CMR in MINOCA; and (iv) whether there are certain groups of MINOCA in whom a CMR should be particularly encouraged or discouraged. If CMR is shown to be beneficial to patients, this is highly likely to influence the way in which future MINOCA patients are assessed.

***Why have I been approached?***

You have been invited to participate in the study because you have come to hospital with a suspected heart attack and a coronary angiogram has shown no obstruction in the blood vessels. Your doctor is therefore planning to organise a CMR as a part of your standard care. Within the UK we plan to recruit at least 60 patients with MINOCA from The James Cook University Hospital, Middlesbrough. Your CMR test may happen in The James Cook University Hospital, or in your local hospital.

***What would my participation entail?***

Your treatment will be completely unchanged. Before you have the CMR, we will ask your doctor to fill in a standard questionnaire regarding the working diagnosis and management. Then, after the CMR is reported, they will fill in the same questionnaire, which will be compared side-by-side with the first questionnaire. You do not need to complete any questionnaires. However, at 12 months following your hospital admission you will be contacted by a member of research team either by telephone or in person. We may also review your medical records to see if you have had any relevant admissions to hospital.

We would also like to have your permission to perform further analyses in the future, using the data gathered in this study. This means that if new research questions arise in the future on MINOCA and CMR which we have not already thought of, we would want to answer those questions using this data rather than repeating a new study.

***Do I have to take part?***

No. Participation is entirely voluntary and in no way impacts upon your usual care. You can choose to end your participation in this research at any time without having to provide a reason.

***What are the risks or burdens to me if I participate?***

No additional investigation or treatment is being proposed by the research beyond what you would normally have received, therefore there are no health-care related risks of participating in the research. The potential burden to you is the time required to complete the interview at 12 months either in person or by telephone where a research member will check if you have had any further heart problems or bleeding problems.

***What will happen with the data collected?***

The lead investigator for the study is Dr. Adil Rajwani in Perth, Western Australia. Co-investigator for the study in the UK is Dr. David Austin at The James Cook University Hospital, Middlesbrough. The research team from the James Cook University Hospital will use the information from you and your medical records to undertake the study and will act as a data controller for this study. This means that we are responsible for looking after your information.

Your name, NHS number and contact details will be kept confidential at The James Cook University Hospital and will not be passed on. Each participant will be assigned a unique research identifier code. A master log with participant details will be kept on a password protected electronic spreadsheet. The James Cook University Hospital will keep identifiable information about you from this study for a period of 5 years after the study has finished. It will be confidentially and securely destroyed after that point.

The findings from the questionnaires completed by your doctor will also be stored under a coded (“de-identified”) form within an encrypted file on a password-protected hospital computer in a locked office, accessible only to research staff. Coded data means that your clinical records will, for the purpose of this study, be stored against a unique study number, and not identifiers like your name.

The final analysis of the de-identified data will be led by the lead investigator Dr Rajwani in Perth, Western Australia.

***What will happen at the end of the project?***

We will present data from the study at national research and scientific forums, and we will publish the results at appropriate national congress meetings and scientific journals. All data will remain anonymised, and your name will not be listed in any presented material.

***Who is organising and funding the research?***

Funding for the administration of the study is from a research grant that was awarded by the Royal Perth Hospital Medical Research Foundation. This grant was awarded on merit during competitive selection from a number of other grants. The chief (overall) investigator is Dr Adil Rajwani (Consultant Cardiologist).

***Contacts for further information***

For further information regarding the study, to tell us that you would like to withdraw from the study or if you wish to discuss any matters related to the study with a member of the research team, please contact us as detailed below:

Dr David Austin, Consultant Cardiologist

The James Cook University Hospital,

Marton Road,

Middlesbrough,

TS4 3BW

Telephone number 01642 282410

Or

Anthony Donnelly, Research Co-ordinator

The James Cook University Hospital

Marton Road

Middlesbrough

TS4 3BW

Telephone number 01642 282410

This project has been granted ethical approval by the Tyne and Wear South NHS Research Ethics Committee for England.

**The James Cook University Hospital**

**CONSENT FORM**

**The MINOCA CMR study**

 Please initial box

1. I confirm that I have read the Participant Information Sheet for the above study. I have had the opportunity to consider the information, ask questions and I am satisfied with the answers I have received.
2. I understand the purposes, procedures and risks of the research project.
3. I understand that relevant sections of my medical records will be looked at by individuals from the research team, regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research.
4. I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the research team at the James Cook University Hospitalconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential and anonymised.
5. I freely agree to participate in this project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
6. I understand that I will be given a signed copy of this document to keep.

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|  |
|  | **Name of Participant (please print)** |  |  |
|  |
|  | **Signature** |  |  **Date** |  |  |
|  |

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| --- |
|  |
|  | **Name of Study Doctor/****Senior Researcher†** **(please print)** |  |  |
|  |  |
|  | **Signature** |  |  **Date** |  |  |
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*† A senior member of the research team must provide the explanation of and information concerning the research project. A copy of this Consent Form should be stored in the participant’s medical record*

**The James Cook University Hospital**

**FORM FOR WITHDRAWAL OF PARTICIPATION**

**The MINOCA CMR study**

**If you wish to withdraw, please sign below to indicate the following:**

I wish to withdraw from participation in all aspects of the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the James Cook University Hospital.

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher must describe the circumstances:

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.