

# Use of Cardiac MRI in patients with presumed heart attack and unobstructed coronary arteries

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| <b>Submission date</b><br>11/12/2020   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>23/02/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>16/06/2025       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

MINOCA CMR is a clinical study evaluating the impact of Cardiac Magnetic Resonance (CMR) imaging on the management of patients with MINOCA (myocardial infarction with non-obstructed coronary arteries). 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 2/3 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.

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.

Who can participate?

Patients who have come to hospital with a suspected heart attack and a coronary angiogram has shown no obstruction in the blood vessels will be eligible to participate in the study.

What does the study involve?

No additional investigation or treatment is being proposed by the research beyond what is normally received.

What are the possible benefits and risks of participating?

None

Where is the study run from?

1. Royal Perth Hospital (Australia)
2. James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?

November 2018 to January 2024

Who is funding the study?

Royal Perth Hospital Medical Research Foundation (Australia)

Who is the main contact?

Dr David Austin  
Anthony Donnelly

## Contact information

### Type(s)

Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

255358

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

CPMS 44931, IRAS 255358

## Study information

**Scientific Title**

The Incremental value of cardiac magnetic resonance (CMR) imaging for clinical decision-making in myocardial infarction with non-obstructive coronary arteries (MINOCA)

**Acronym**

CMR in MINOCA V1.0

**Study objectives**

An evaluation of the clinical role of Cardiac MRI in patients with non-obstructed coronary arteries with regards to the frequency of change in diagnostic certainty and management

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 17/11/2020, North East – Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8084; tyneandwearsouth.rec@hra.nhs.uk), ref: 20/NE/0218

## **Study design**

Observational

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Clinical decision-making in myocardial infarction with non-obstructive coronary arteries

## **Interventions**

The questionnaire to the treating consultant seeks to determine:

- (a) the current working diagnosis;
- (b) certainty of diagnosis (Underlying aetiology felt to be plaque rupture, or uncertain [defined as a diagnostic certainty for the underlying mechanism reported by the treating clinician of  $\leq 7$  out of 10, where 1 is fully uncertain and 10 is fully certain])
- (c) detailed capture of the management, encompassing in particular all medications, all further tests planned/deferred, plans for future follow-up, and planned family screening.

In order to document patient characteristics that may be predictors of a diagnostic / non-diagnostic CMR study, relevant parameters will be determined by the research team from the case notes / electronic records. These will include parameters such as age, gender, symptoms and observations at presentation, troponin elevation magnitude, angiographic findings, whether intra-vascular coronary imaging was performed, echocardiographic findings, ECG findings at presentation, past medical history, GRACE score of future cardiovascular risk in acute coronary syndromes, and others.

Where the clinical scenario evolves such that MINOCA ceases to be the correct label and that a Type II myocardial infarction is instead the correct presentation (a not-uncommon scenario as the patient history evolves during inpatient stay), the participant will exit the study. This is because Type II infarction is regarded as a different clinical entity from MINOCA. No research data will be retained for such patients as they are regarded as not fulfilling the inclusion criteria.

The conduct of the CMR will be in accordance with the institution's own standard protocol rather than a fixed research protocol, but will be expected to broadly align with international standards such as those detailed in the "SCMR board of trustees task force on standardized protocols (2016)". Study sites will be encouraged to perform CMR studies within approximately 2 weeks of presentation, as this is thought to maximise clinical yield.

Following the CMR, the treating consultant will again be asked to complete a questionnaire regarding diagnosis, diagnostic certainty and all aspects of management, but this 2nd questionnaire will now be completed AFTER receipt of the CMR report.

Finally, a telephone or in-person consultation of the participant will be conducted at 1 year post presentation, to determine whether there have been any hospitalisation, cardiovascular or bleeding adverse events over the 12 months.

Sample size is set at 384. This will allow prevalence of the primary endpoint (the composite of change in diagnosis or management) to be estimated such that their Confidence Intervals will be no wider than +/-5%, assuming a conservative 50% prevalence for there being a change consequent to the CMR.

Data analysis will be performed at the conclusion of the study. For diagnosis, the paired pre-versus post-CMR diagnostic labels (from the exhaustive list of 10 aetiologies + "other (please specify)") will be tabulated, compared and quantified for frequency of change (McNemars test). A further analysis will also determine which pre-CMR diagnoses were most/least susceptible to change. Diagnostic certainty is selected from 1 (very uncertain) to 10 (highly certain). Change in diagnostic certainty pre- versus post-CMR will be tested for significance by Student's paired t-test.

Interaction of change in certainty with pre-CMR (un)certainty will also be explored. Management changes will be multiparametric covering (i) pharmacotherapy, (ii) further tests indicated / abandoned, and (iii) future outpatient follow-up, with similar analyses to diagnostic label change. Change in any one parameter is clinically significant however, thus multiple changes are not hierarchical over single change. As per section A1, the composite of change in diagnosis or management forms the primary endpoint, and individual components will form the first 3 secondary outcomes. Univariate predictors of a diagnostic CMR study will be determined by logistic regression, with receiver-operating curve used to determine the sensitivity and specificity for continuous variables such as serum troponin. Health economic analyses detailed in the proposal will be performed with Health Economics Professor Elizabeth Geelhoed (University of Western Australia).

## **Intervention Type**

Other

## **Primary outcome(s)**

Diagnosis and management assessment completed by the treating cardiologist before and after the patient has undergone the cardiac MRI (questionnaire assessment of working diagnosis, diagnostic certainty [scale 1 - 10] and clinical management)

## **Key secondary outcome(s)**

Assessment completed by the treating cardiologist before and after the patient has undergone the cardiac MRI (questionnaire assessment of working diagnosis, diagnostic certainty [scale 1 - 10], and clinical management):

1. Diagnosis
2. Diagnostic certainty
3. Management
4. Incidence of recurrent myocardial infarction at 1 year measured using patient records
5. Incidence of clinically-significant bleeding (Bleeding Academic Research Consortium (BARC) Type II, III or V) at 1 year measured using patient records

**Completion date**

06/01/2024

## Eligibility

**Key inclusion criteria**

1. Presentation with MINOCA (as per the 2016 ESC consensus statement definition)
2. Presence of diagnostic uncertainty\* as to the underlying mechanism.
3. Treating clinician intends to further assess by CMR
4. Age >18 years

\*Diagnostic uncertainty is defined as at least some doubt on the part of the treating clinician as to the underlying mechanism for the MINOCA, and quantified as a certainty level  $\leq 8$  (range 1-10, with 1 being fully uncertain and 10 being fully certain)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

82

**Key exclusion criteria**

1. Treating cardiologist deems the diagnosis is already felt to be secure ( $\geq 9$  of the certainty scale which has a range 1-10)
2. CMR is contra-indicated or not planned
3. Type II myocardial infarction rather than MINOCA
4. Symptom onset >2 weeks prior to CMR
5. Pregnancy
6. Does not have capacity to consent

**Date of first enrolment**

04/02/2021

**Date of final enrolment**

31/01/2023

## Locations

**Countries of recruitment**

United Kingdom

England

Australia

**Study participating centre**

**James Cook University Hospital**

South Tees Hospitals NHS Foundation Trust

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United Kingdom

TS4 3BW

**Study participating centre**

**Darlington Memorial Hospital**

County Durham and Darlington NHS Foundation Trust

Hollyhurst Road

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**Study participating centre**

**University Hospital of Hartlepool**

North Tees and Hartlepool NHS Foundation Trust

Holdforth Road

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TS24 9AH

**Study participating centre**

**Royal Perth Hospital**

Victoria Square

Perth

Australia

6000

## **Sponsor information**

### **Organisation**

## Funder(s)

### Funder type

Charity

### Funder Name

Royal Perth Hospital Medical Research Foundation

### Alternative Name(s)

Royal Perth Hospital Medical Research Foundation Incorporated, RPH Medical Research Foundation Inc., Medical Research Foundation, Royal Perth Hospital Medical Research Foundation Inc., RPH-MRF, RPH MRF

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Australia

## Results and Publications

### Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

| Output type                                   | Details      | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|--------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |              | 13/06/2025   | 16/06/2025 | Yes            | No              |
| <a href="#">HRA research summary</a>          |              |              | 28/06/2023 | No             | No              |
| <a href="#">Participant information sheet</a> | version v1.1 | 26/10/2020   | 23/02/2021 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version v1   | 27/07/2020   | 23/02/2021 | No             | No              |