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

Submission date
11/12/2020

Recruitment status
No longer recruiting

Registration date
23/02/2021

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 <=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 ≤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 (≥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
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Study participating centre
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County Durham and Darlington NHS Foundation Trust
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Study participating centre
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Study participating centre
Royal Perth Hospital
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Sponsor information

Organisation

South Tees Hospitals NHS Foundation Trust

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?
Results article		13/06/2025	16/06/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version v1.1	26/10/2020	23/02/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1	27/07/2020	23/02/2021	No	No