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The role of MRI in heart attacks with normal heart arteries

Submission date
31/01/2019

Recruitment status
No longer recruiting

Registration date
06/02/2019

Overall study status
Completed

Last Edited
10/02/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
90% of heart attacks are caused by blocked or narrowed heart arteries. However up to 10% of patients do not have a primary problem with their heart arteries. These patients are now classified as having ‘MINOCA’ (myocardial infarction with non-obstructive coronary arteries). These patients were thought to be low risk and were often discharged with no treatment or follow up. However, they have a 12-month mortality approaching 5%. The majority of these patients have one of three conditions: inflammation of the heart (myocarditis), stress cardiomyopathy (takotsubo cardiomyopathy) or a missed heart attack. Cardiac MRI is very good at identifying between these causes. There is a link between the heart and brain and this is a very ‘hot topic’ in cardiology at the moment. It has been shown in small, retrospective studies that patients who have stress cardiomyopathy have certain structural and functional differences in their brain compared to people who do not develop this condition in response to stress. In this study functional brain MRI is performed at the time of cardiac MRI to study this prospectively for the first time. The aims are to improve the diagnostic pathway of patients with MINOCA compared to standard practice, and to acquire pilot data showing structural and functional brain differences in patients with stress cardiomyopathy.

Who can participate?
Patients of any gender between the ages of 18 and 80 who present to the Bristol Heart Institute with MINOCA, and control patients of any gender between 18 and 80 who present to the Bristol Heart Institute with a myocardial infarction with obstructive coronary artery disease.

What does the study involve?
The study involves four 'visits'. The first visit is as an inpatient and involves multiple questionnaires, a brain and heart MRI scan. The second visit is at 4-6 weeks and involves a heart tracing, blood test, heart MRI scan and ultrasound of the heart. The third visit is at 6 months and involves questionnaires, heart racing, heart and brain MRI, ultrasound of the heart and blood tests. The final visit is a phone call at 12 months to see how the participants are doing. The study is the same for the control patients excluding the second visit.

What are the possible benefits and risks of participating?
There may be no direct benefit to patients from participating in this study. However, it will

hopefully improve care for similar patients in the future. The main risks from participating in this study is the chance of finding 'incidental' abnormal findings on heart and brain imaging. If this is the case this information and recommendations are passed onto the participant's GP or cardiologist for further action.

Where is the study run from?
Bristol Heart Institute (UK)

When is the study starting and how long is it expected to run for?
February 2018 to January 2021

Who is funding the study?
The James Tudor Foundation

Who is the main contact?
Dr Matthew Williams
MINOCA@uhbristol.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Matthew Williams

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018/2138

Study information

Scientific Title

The Incremental role of MRI in myocardial infarction with non-obstructive coronary arteries

Acronym
MINOCA

Study objectives
90% of heart attacks are caused by blocked or narrowed heart arteries. However up to 10% of patients do not have a primary problem with their heart arteries. These patients are now classified as having 'MINOCA' (myocardial infarction with non-obstructive coronary arteries). These patients were thought to be low risk and were often discharged with no treatment or follow up. However, they have a 12-month mortality approaching 5%. The majority of these patients have one of three conditions: inflammation of the heart (myocarditis), stress cardiomyopathy (takotsubo cardiomyopathy) or a missed heart attack. Cardiac MRI is very good at identifying between these causes.

There is a link between the heart and brain and this is a very 'hot topic' in cardiology at the moment. It has been shown in small, retrospective studies that patients who have stress cardiomyopathy have certain structural and functional differences in their brain compared to people who do not develop this condition in response to stress. As an additional sub-study we will be performing functional brain MRI at the time of cardiac MRI in our participants to study this prospectively for the first time.

The aims of this study are:
1. To improve the diagnostic pathway of patients with MINOCA compared to standard practice.
2. To acquire pilot data showing structural and functional brain differences in patients with stress cardiomyopathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Hampshire B Research Ethics Committee, Level 3 Block B, Whitefriars, Lewins Mead, Bristol
BS1 2NT, Tel: +44 (0)207 104 8052, Email: nrescommittee.southcentral-hampshireb@nhs.net, 21/08/2018, ref: 18/SC/0380

Study design
Prospective observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request participant information sheet.

Health condition(s) or problem(s) studied
Myocardial Infarction with Obstructive Coronary Arteries (MINOCA)

Interventions
Patients undergo sequential echo, cardiac and brain MRI scanning, blood tests and psychological testing as an inpatient at 6 weeks and at 6 months. The trialists will look for changes in clinician's diagnosis before and after cardiac MRI and the psychological, anatomical and functional differences between patients with takotsubo cardiomyopathy and control patients. This will help tailor treatments to each patient and improve patient experience and outcomes.

Intervention Type
Other

Primary outcome measure
Change in clinical diagnosis or change in clinical management measured via questionnaire at baseline

Secondary outcome measures
1. CMR mechanistics (LV function/volumes, presence and amount of oedema, native T1/T2 values, speckle tracking values, late gadolinium presence and pattern) measured at baseline, 6 weeks and 6 months
2. Differences in structural or resting functional brain MRI parameters in MINOCA patients compared to controls, measured at baseline and 6 months
3. All-cause mortality, cardiovascular readmissions (myocardial infarction, angina, heart failure, stroke), measured at 12 months

Overall study start date
07/02/2018

Completion date
31/01/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 10/02/2020:
1. Aged 18 to 80 years
2. Meets the ESC universal definition of myocardial infarction
3. <50% epicardial coronary artery stenosis on invasive or CT coronary angiography in any potential infarct-related territory
4. No other clinically overt specific cause for the acute presentation at the time of angiography
5. Written informed consent

Previous participant inclusion criteria:
1. Age 18-75 years
2. They meet the ESC universal definition of myocardial infarction
3. <50% epicardial coronary artery stenosis on invasive or CT coronary angiography in any

potential infarct related territory
4. No other clinically overt specific cause for the acute presentation at the time of angiography
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
150 (100 patients and 50 controls)

Key exclusion criteria
Current participant exclusion criteria as of 10/02/2020:
1. Invasive or CT coronary angiography not performed or not diagnostic
2. Contraindications to MRI
3. Pregnant or breastfeeding
4. Prisoners
5. Unable to meet the follow-up requirements.
6. Timing of the initial CMR of >2 weeks after presentation
7. Previous CABG (coronary artery bypass graft)

Previous participant exclusion criteria:
1. Invasive or CT coronary angiography not performed or not diagnostic
2. Contraindications to MRI
3. Pregnancy or breastfeeding
4. Prisoners
5. Patients unable to meet the follow up requirements.
6. Timing of the initial CMR of >2 weeks after presentation

Date of first enrolment
31/01/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Heart Institute
Cardiac MRI Unit (C502)
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BS2 8HW

Sponsor information

Organisation
University of Bristol

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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
James Tudor Foundation

Results and Publications

Publication and dissemination plan
The results will be published in peer reviewed journals and presented at relevant national /international conferences.

Intention to publish date
31/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the chief or primary investigators. Data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. The second file containing patient identifiers would be made available for record linkage or a similar purpose, subject to confirmation that the secondary research protocol has been approved by a UK REC or other similar, approved ethics review body. Contact details will be made available at the end of the study. Patients have been consented for the use of their anonymised data in future studies.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No