# Clinical evaluation of MAgnetic Resonance imaging in Coronary heart disease

Submission date Recruitment status [X] Prospectively registered 07/02/2006 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 21/02/2006 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 17/07/2015 Circulatory System

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr JP Greenwood

#### Contact details

Senior Lecturer & Consultant Cardiologist
Leeds University & Leeds Teaching Hospitals NHS Trust
Department of Cardiology
G Floor, Jubilee Wing
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 392 5404
j.greenwood@leeds.ac.uk

# Additional identifiers

Protocol serial number

N/A

# Study information

#### Scientific Title

Clinical evaluation of MAgnetic Resonance imaging in Coronary heart disease

#### Acronym

Ce-MARC

#### **Study objectives**

Approximately 2.5 million people in the UK suffer from the symptoms of CHD. Currently patients with CHD undergo a number of tests, including angiography, which carries a small but significant risk. It is anticipated that the new test of Cardiac Magnetic Resonance Imaging (CMRI) will be more reliable in identifying those patients who would benefit from a bypass or angioplasty than current non-invasive tests.

This research programme will include the first large-scale prospective evaluation of a validated comprehensive CMRI imaging protocol compared to the standard non-invasive tests Exercise Treadmill Testing (ETT) and Single Photon Emission Computed Tomography (SPECT) for the diagnosis of suspected Coronary Heart Disease (CHD) with x-ray coronary angiography as the reference standard. Patient follow up will provide much needed prognostic data for CMRI, and a health economic evaluation and assessment of patient preference will be performed for the different investigation strategies.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the Leeds West Research Ethics Committee, 24/08/2005, ref: 05/Q1205/126

#### Study design

Randomised cross-over study

## Primary study design

Interventional

# Study type(s)

Diagnostic

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

Coronary heart disease

#### Interventions

Comparing non-invasive techniques for diagnosing coronary artery disease (ETT, SPECT and CMR) against invasive angiography. Patients who agree to take part in the study will initially undergo three investigations: ETT and then in random order, cardiac Magnetic Resonance Imaging (MRI) and SPECT imaging. After all three tests have been completed, all patients will undergo x-ray angiography.

#### Intervention Type

Other

#### Phase

## Primary outcome(s)

The diagnostic performance of MRI to detect significant CHD on x-ray angiography

## Key secondary outcome(s))

- 1. The diagnostic performance of current standard clinical investigations of ETT and SPECT
- 2. The cost effectiveness of CMRI in a diagnostic strategy for the systematic investigation of patients with suspected CHD
- 3. Patient's preference of the different strategies for the investigation of suspected CHD

## Completion date

27/02/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Ages between 35 and 79 years
- 2. Weight less than 110 kg
- 3. Suitable for coronary revascularisation if required
- 4. Clinically stable
- 5. In sinus rhythm

#### Participant type(s)

Patient

# Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Previous revascularisation
- 2. Evidence of crescendo angina or acute coronary syndrome
- 3. Contraindication to MRI imaging (pacemaker, intraorbital debris, intraauricular implants, intracranial clips)
- 4. Contraindication to adenosine infusion (regular adenosine antagonist medication, asthma /chronic obstructive pulmonary disease, second or third degree atrioventricular heart block, sinoatrial disease)
- 5. Aged less than 35 years
- 6. Weight greater than 100 kg
- 7. Non-sinus rhythm
- 8. Resting heart rate greater than 100 /min
- 9. Frequent ventricular ectopy (greater than 3 Ventricular Premature Beats [VPB] per minute)
- 10. Pregnancy
- 11. Known adverse reaction to adenosine or gadolinium contrast agent

- 12. Inability to lie supine for 60 minutes
- 13. Known chronic renal insufficiency

# Date of first enrolment

27/02/2006

#### Date of final enrolment

27/02/2011

# Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre Leeds University & Leeds Teaching Hospitals NHS Trust

Leeds United Kingdom LS1 3EX

# Sponsor information

#### Organisation

**British Heart Foundation** 

#### **ROR**

https://ror.org/02wdwnk04

# Funder(s)

# Funder type

Charity

#### **Funder Name**

British Heart Foundation (UK)

#### Alternative Name(s)

the\_bhf, The British Heart Foundation, BHF

# **Funding Body Type**

# Private sector organisation

# **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

#### Funder Name

Leeds General Infirmary (LGI) Challenge Fund (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	11/03/2014	Yes	No
Results article	results	15/07/2015	Yes	No
Protocol article	protocol	29/07/2009	Yes	No
Other publications	prospective trial	04/02/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes
Study website	Study website	11/11/2025 11/11/2025	No	Yes