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Clinical evaluation of MAgnetic Resonance imaging in Coronary heart disease

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.leedscmr.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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
Not Specified

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

Secondary outcome measures
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

Overall study start date
27/02/2006

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

Age group
Adult

Sex
Both

Target number of participants
750

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, sino-atrial 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
England

United Kingdom

Study participating centre
Leeds University & Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation

British Heart Foundation

Sponsor details
14 Fitzhardinge Street
London
United Kingdom
W1H 6DH
+44 (0)207 9350185
research@bhf.org.uk

Sponsor type
Charity

Website
http://www.bhf.org.uk/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	29/07/2009		Yes	No
Other publications	prospective trial	04/02/2012		Yes	No
Results article	results	11/03/2014		Yes	No
Results article	results	15/07/2015		Yes	No