ISRCTN53688797 https://doi.org/10.1186/ISRCTN53688797

Myocardial perfusion with an intravascular contrast agent

Submission date 03/04/2009	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 13/11/2009	**Overall study status** Stopped	
Last Edited 14/06/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Eike Nagel

Contact details
The Rayne Institute - Division of Imaging Sciences
School of Medicine - King's College London
4th Floor, Lambeth Wing
St. Thomas Hospital
London
United Kingdom
SE1 7EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
25/11/2008 Final_v1.1

Study information

Scientific Title
Quantitative assessment of myocardial perfusion with magnetic resonance using an intravascular contrast agent: an open label trial

Study objectives
The primary objective of the trial will be to develop and evaluate new methods for the true quantitative measurement of blood supply to the heart using cardiac magnetic resonance (MR) and gadolinium-based MR contrast agents.

The secondary objectives of the trial will be:
1. To optimise the MR sequence parameters for the acquisition of MR first pass perfusion images
2. To determine the best dosage and scheme of administration for the intravascular MR contrast agent Vasovist®
3. To compare the results obtained with different types of contrast agents and different MR sequences
4. To validate the newly developed methods for quantitative measurement of myocardial perfusion against 13N-Ammonia positron emission tomography (PET) and with fractional flow reserve (FFR)
5. To test the reproducibility of the different MR approaches to quantitative myocardial perfusion assessment

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS National Research Ethics Service - Guy's Research Ethics Committee approved on the 29th February 2009 (ref: 08/H0804/95; Protocol v.1.1)

Study design
Non-randomised non-controlled open label trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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 artery disease

Interventions
14/06/2013: Please note that this trial was stopped in April 2011.

First pass perfusion magnetic resonance during stress with intravenous (i.v.) adenosine.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Adenosine, Vasovist®

Primary outcome measure
1. Comparison and validation of Vasovist® perfusion MR versus conventional perfusion MR, PET and FFR:
1.1. Comparison between standard clinical qualitative evaluation of MR perfusion and fully quantitative evaluation
1.2. Validation against 13N-Ammonia PET (research indication) and/or FFR (only performed following a clinical indication as part of routine clinical care)
2. Reproducibility of Vasovist® first pass MR perfusion: comparison of the results between different perfusion MR scans

Secondary outcome measures
1. MR sequence optimisation for Vasovist® perfusion:
1.1. Signal to noise ratio in the images acquired with different MR techniques
1.2. Prevalence of artefacts in the images
2. Vasovist® dose selection:
2.1. Saturation effect of the peak contrast agent signal in the myocardium
2.2. Signal to noise ratio
2.3. Prevalence of artefacts in the images

Overall study start date
15/04/2009

Completion date
28/02/2010

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Known coronary artery disease (with or without prior percutaneous revascularisation)
2. Indication for percutaneous coronary intervention (PCI)
3. The subject is 18 years of age or older, either sex

4. The subject is conscious and able to comply with study procedures
5. Written informed consent has been obtained

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
156

Key exclusion criteria
1. Contraindications for magnetic resonance imaging (MRI)
2. Contraindications to gadolinium-based contrast agents (known allergies or a contra-indication to gadolinium (Gd) chelates or renal insufficiency)
3. Contraindications to adenosine stress:
3.1. Myocardial infarction less than 3 days
3.2. Unstable angina pectoris
3.3. Severe arterial hypertension
3.4. Asthma or severe obstructive pulmonary disease requiring treatment (chronic obstructive pulmonary disease [COPD])
3.5. Sick sinus syndrome or a symptomatic bradycardia, atrioventricular (AV) block greater than IIa, trifascicular block
3.6. Allergy against vasodilator
3.7. Allergy against gadolinium-based contrast agents or renal insufficiency
3.8. Other contraindications for adenosine or dipyridamole administration
4. The subject has significant cardiac arrhythmia (i.e. atrial fibrillation)
5. Pregnancy
6. Heart failure (New York Heart Association [NYHA] grade IV)
7. The subject's electrocardiogram (ECG) shows prolonged QT interval
8. Severe arterial hypotension (less than 90 mmHg systolic)
9. Claustrophobia

Date of first enrolment
15/04/2009

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Rayne Institute - Division of Imaging Sciences
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London (UK)

Sponsor details
The Rayne Institute
4th Floor Lambeth Wing
St Thomas' Hospital
London
England
United Kingdom
SE1 7EH

Sponsor type
University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
Bayer Schering Pharma AG (Germany)

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?
HRA research summary			28/06/2023	No	No