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Improved diagnosis of Congenital Heart Disease by magnetic resonance imaging using Vasovist

Submission date	Recruitment status	[_] Prospectively registered
29/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/04/2012	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00668824

Protocol serial number
1

Study information

Scientific Title

Acronym
CHD Vasovist

Study objectives
Magnetic Resonance Imaging (MRI) is an effective and radiation free method of diagnosing Congenital Heart Disease (CHD). MRI works by taking images of the anatomy and physiology. These images also provide information on the hearts function and blood flow. The clarity of these images is enhanced by the use of contrast agents (dyes). However these agents only stay in the blood vessels for a short time and therefore limit the time in which the better quality images can be obtained. This study aims to determine whether MRI using Vasovist (a dye that stays in the vessels for a prolonged period of time) can improve the diagnosis of Congenital Heart Disease (CHD) by allowing more areas to be imaged and the improved assessment of various parameters (anatomy, volumes, flow) as well as vastly improving image quality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Guy's Research Ethics Committee on the 7th March 2007 (ref: 07 /Q0704/2).

Study design
Non-randomised non-controlled clinical trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Congenital Heart Disease (CHD)

Interventions
We planned an intra-individual study, where 20 adult patients with CHD (e.g. Fallot Tetralogy, s /p corrective surgery, single ventricle s/p Fontan operation, aortic and pulmonary artery stenosis) will undergo two examinations. Both scans are aimed to assess different diagnostic parameter like angiography, cardiac anatomy, ventricular volume and flow.

The first clinically indicated scan in our clinically established imaging protocol is performed using a standard contrast agent. The second scan is performed using a new protocol with Vasovist within the next seven days. Informed consent for the additional second scan will be obtained. In order to optimise the scan protocol for Vasovist we plan a pilot phase using three patients. Dosage of the two contrast agents will be within the approved dose. Any adverse events will be immediately reported. The following diagnostic parameters will be assessed and compared between standard Gadolinium (Gd) agent and Vasovist.

1. MR-Angiography (MRA): assessment of the MRA quality of the large systemic and the pulmonary vessel (arterial and venous) by measuring the Contrast-to-Noise Ratio (CNR) and the vessel sharpness. In addition, the overall image-quality will be scored by three independent readers (scale: excellent, good, ok, bad).

2. Cardiac Anatomy: assessment of image quality of the cardiac anatomy from 3D single/dual phase MRI by measuring Signal-to-Noise Ratio (SNR) and CNR as well as assessing the overall image quality by three independent readers (scale: excellent, good, ok, bad).
3. Ventricular Volumes: comparison of systolic and diastolic volumes measured from multi-slice 2D short axis cine MRI, two single phases 3D whole heart MRI (diastole and systole).
4. Flow: the different flow values will be measured in the large vessels using the Phase Contrast Angio (PCA) data. Furthermore, the flow reproducibility will be determined by using two scans.
The overall scan-time to assess all these parameter will be approximately 40 minutes. The intra-individual study allows a direct comparison of the different parameters in a number of vascular territories.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vasovist

Primary outcome(s)
1. The improvement of diagnosis of CHD, due to larger coverage of vascular territories, higher spatial resolution, faster acquisition and higher quality of MR-flow measurements using Vasovist in comparison with standard Gd-agent
2. The improvement of image quality will be analysed by measuring the SNR, the CNR, the vessel sharpness. In addition, the overall image quality will be scored by three independent readers (scale: excellent, good, ok, bad)
3. Ventricular volumes measured from the acquired data will be compared with respect to a reference
4. The accuracy (standard deviation) and reproducibility of the flow measurements will be compared using the two different agents

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/07/2008

Eligibility

Key inclusion criteria
The main inclusion criteria will be patient with CHD, i.e. complex congenital defects such as:
1. Aortic abnormalities
2. Pulmonary artery abnormalities
3. Systemic or pulmonary venous abnormalities
4. The study will be limited to patients aged 18 and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
The study will involve MR contrast agents and and MRI scans, therefore the principle exclusion criteria are:
1. Any contra-indications to MR (e.g. pacemakers)
2. Known allergy to MR contrast agents
3. Patients not agreeing to take part in study
4. Pregnancy and nursing mothers

Date of first enrolment
01/03/2007

Date of final enrolment
30/07/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imaging Sciences
London
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Sponsor information

Organisation
Guy's Hospital (UK)

ROR

https://ror.org/04r33pf22

Funder(s)

Funder type
Industry

Funder Name
Schering (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	01/09/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes