

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

Submission date 29/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/03/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/04/2012	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00668824

Secondary identifying numbers
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

Secondary study design

Single-centre

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

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/03/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

The study will involve MR contrast agents 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

England

United Kingdom

Study participating centre

Imaging Sciences

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Guy's Hospital (UK)

Sponsor details

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SE1 9RT

Sponsor type

Hospital/treatment centre

Website

<http://www.guysandstthomas.nhs.uk/home.aspx>

ROR

<https://ror.org/04r33pf22>

Funder(s)

Funder type

Industry

Funder Name

Schering (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?
Results article	results	01/09/2011		Yes	No