A comparison of the effects of Sevoflurane and Isoflurane on cardiovascular parameters measured by cardiac magnetic resonance imaging in paediatric patients with congenital heart disease. A randomised controlled trial.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2005		Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2005	Completed	[X] Results		
Last Edited 15/07/2009	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0013145919

Study information

Scientific Title

Study objectives

Sevoflurane and isoflurane are commonly used to anaesthetise patients with congenital heart disease. Which agent causes the least depression of cardiac function?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Heart disease

Interventions

The routine study usually lasts 1 hour. For the first 30 minutes, each subject will be anaesthetised with one of the agents. The agent will then be swapped and the patients anaesthetised with the other agent for the remaining 30 minutes. Variables will be recorded at the end of each period.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Cardiac output, aortic and pulmonary blood flow, arterial pressure, systemic vascular resistance.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2003

Completion date

01/09/2004

Eligibility

Key inclusion criteria

Subjects will be children with congenital cardiac abnormalities who are undergoing magnetic resonance imaging to achieve an accurate diagnosis and determine future treatment options.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

10

Key exclusion criteria

- 1. Patient or parental refusal
- 2. Allergic, anaphylactic or other reactions to inhalational anaesthetic agents
- 3. Patients older than 16 years of age.

Date of first enrolment

01/09/2003

Date of final enrolment

01/09/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Theatres

London United Kingdom SE1 9RT

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK) Own account, NHS R&D Support Funding

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2008		Yes	No