# 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	<ul><li>Prospectively registered</li></ul>		
30/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2005	Completed	[X] Results		
<b>Last Edited</b> 15/07/2009	<b>Condition category</b> 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

Protocol serial number 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

#### Study type(s)

Other

#### 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(s)

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

#### Key secondary outcome(s))

Not provided at time of registration

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Child

#### Sex

All

#### 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

United Kingdom

England

## Study participating centre

#### Theatres

London United Kingdom SE1 9RT

# Sponsor information

#### Organisation

Department of Health

# 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**

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	01/02/2008		Yes	No