ISRCTN81324728 https://doi.org/10.1186/ISRCTN81324728

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Priti Dalal

Contact details
Theatres
2nd Floor, New Guy House
Guy's Hospital
St Thomas' Street
London
United Kingdom
SE1 9RT

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 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