

A comparison of inhalational induction of anaesthesia between incremental doses of sevoflurane and high dose sevoflurane in children under 2 years of age

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 13/03/2014	Condition category Surgery	☐ Individual participant data
		☐ Record updated in last year

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

N0265006729

Study information

Scientific Title

Study objectives

We intend to carry out a prospective, randomised trial comparing the use of incremental or high dose sevoflurane with O₂/N₂O for the induction of children under two years of age, to investigate this observed reaction to sevoflurane. We expect to see bradycardias only in the high dose group. Both methods are standard induction techniques.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anaesthesia in elective surgery

Interventions

With parental consent, all children scheduled to undergo elective surgery who are to receive an inhalational induction will be eligible. Patients will be randomised to receive either incremental or high dose sevoflurane. The rate will be electronically recorded during induction of anaesthesia. Data will be subsequently analysed for alterations of heart rate: severe bradycardia being defined as a 20% reduction in heart rate from the baseline.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sevoflurane

Primary outcome(s)

Data will be subsequently analysed for alterations of heart rate: severe bradycardia being defined as a 20% reduction in heart rate from the baseline.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2007

Eligibility

Key inclusion criteria

Children under two years of age with parental consent, all children scheduled to undergo elective surgery who are to receive an inhalational induction will be eligible.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

2 Years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Anaesthetics

Birmingham

United Kingdom

B15 2TH

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration