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Randomised clinical trial of the effects of Total Intravenous Anaesthesia (TIVA: propofol) versus volatile anaesthesia (sevoflurane-nitrous oxide) on children's post-operative cognition, behaviour and physical morbidity

Submission date 12/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/04/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/04/2016	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

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

Secondary identifying numbers
CZH/4/382

Study information

Scientific Title
Randomised clinical trial of the effects of Total Intravenous Anaesthesia (TIVA: propofol) versus volatile anaesthesia (sevoflurane-nitrous oxide) on children's post-operative cognition, behaviour and physical morbidity

Study objectives
Recovery of children's cognitive function will be quicker, and physical morbidity less, after intravenous compared to volatile anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Ethics Committee of the Western Infirmary, 09/01/2007, ref: 07S07033

Study design
Randomised single centre clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dental caries

Interventions
Children will be randomised to separate groups having general anaesthesia with the intravenous agent propofol, or the volatile agent sevoflurane-nitrous oxide. They will perform child-appropriate tests of reaction time, motor control, attention and memory pre-operatively (baseline), post-operatively prior to discharge, and 48 hours later at home.

Between-group comparisons of performance and of post-operative physical morbidity will test the hypothesis stated above.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sevoflurane-nitrous oxide and propofol

Primary outcome measure
Cognitive performance on tests of reaction time, motor control, attention and memory.

Secondary outcome measures
Physical morbidity assessed by day-surgery staff using a standard protocol at discharge.

Overall study start date
19/03/2007

Completion date
28/02/2010

Eligibility

Key inclusion criteria
1. Male and female children aged seven to 12 years
2. American Society of Anaesthesiologists (ASA) grade I or II
3. Requiring general anaesthesia for multiple dental extractions

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
360

Key exclusion criteria

1. Respiratory disorder
2. Learning disability
3. Non-fluent English
4. Neurological or psychological impairments that would impede cognitive assessment

Date of first enrolment
19/03/2007

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Section of Psychological Medicine
Glasgow
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Sponsor information

Organisation
NHS Glasgow and Clyde/University of Glasgow

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Research and Development Office
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Sponsor type
Government

Website
http://www.nhsgg.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) (Grant ref: CZH/4/382)

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