

# 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

<b>Submission date</b> 12/03/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/04/2016	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

## Primary study design

Interventional

## Study design

Randomised single centre clinical trial

## Study type(s)

Treatment

## 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(s)

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

7 Years

**Upper age limit**

12 Years

**Sex**

All

**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**

United Kingdom

Scotland

**Study participating centre**  
**Section of Psychological Medicine**  
Glasgow  
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G12 0XH

## **Sponsor information**

**Organisation**  
NHS Glasgow and Clyde/University of Glasgow

**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**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration