

Evaluation of propofol target-controlled infusion (TCI) anaesthesia in infants aged 6 months to 3 years

Submission date 16/08/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/08/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/11/2012	Condition category Surgery	<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
2008/PAEDAN/01

Study information

Scientific Title

Study objectives

The "Paedfusor" model performs within recognised acceptable limits of accuracy when used in children in the age group of 6 months to 3 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

To be submitted to West Ethics Committee (Glasgow) in September 2008.

Study design

Interventional, single-arm, single-centre trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Intravenous general anaesthesia in infants and young children

Interventions

Propofol 2% infusion anaesthesia delivered by TCI system using the "Paedfusor" software.

Details of Joint Sponsor:

NHS Greater Glasgow and Clyde

Dalian House

PO Box 15329

350 St. Vincent Street

Glasgow, G3 8YZ

United Kingdom

<http://www.nhsgg.org.uk>

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Propofol

Primary outcome(s)

Performance of the "Paedfusor" pharmacokinetic model for children aged 6 months - 3 years, weight 7-16 kg as calculated from 4 standard parameters (see below). The performance error (PE) is calculated from the concentration of propofol measured in whole blood (C_{meas}) and the concentration predicted by the software (C_{pred}) as follows:

$$PE(\%) = [(C_{meas} - C_{pred})/C_{pred}] \times 100$$

The four standard measures of performance are derived from this value, namely bias, precision, divergence and wobble. These derived parameters estimate whether the system over- or under-delivers propofol, by how much and how this varies between patients and for an individual patient over time. The blood propofol samples will be taken throughout surgery and one sample 4 hours afterwards.

Key secondary outcome(s)

Population pharmacokinetics of propofol in children aged 6 months - 3 years, calculated using non-linear effects modelling (NONMEM). This allows calculations of volume of distribution and clearance of propofol, and any relationships between these pharmacokinetic parameter values and patients age, gender and weight to be statistically evaluated.

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Healthy male and female children aged 6 months - 3 years (inclusive)
2. Weight 7-16 kg
3. Elective surgery of expected duration ≥ 30 minutes
4. American Society of Anaesthesiologists (ASA) Grade 1 or 2
5. Written informed consent from parent
6. Child suitable for intravenous induction and maintenance of anaesthesia with propofol
7. Children with no contraindication to application of local anaesthetic cream or gel to the cannulation site for intravenous induction

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

3 years

Sex

All

Key exclusion criteria

1. Age < 6 months or > 3 years (> 36 months)
2. Weight < 7 kg or ≥ 17 kg
3. Children undergoing urgent or emergency surgical procedures

4. Expected duration of surgery <30 minutes
5. ASA Grade 3-5
6. No written informed consent from parent
7. Children with difficult venous access
8. Children who need or wish inhalational induction
9. Children who will need intermittent positive pressure ventilation along with the use of muscle relaxant
10. Patients who need sedative premedication
11. Propofol contraindicated (allergy to propofol or its formula components)
12. Local anaesthetic cream or gel contraindicated

Date of first enrolment

01/11/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Department of Anaesthesia

Glasgow

United Kingdom

G3 8SJ

Sponsor information

Organisation

University of Glasgow (UK)

ROR

<https://ror.org/00vtgdb53>

Funder(s)

Funder type

Industry

Funder Name

Cardinal Health (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration