

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

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

**Contact name**  
Dr Neil Morton

**Contact details**  
Department of Anaesthesia  
Royal Hospital for Sick Children  
Glasgow  
United Kingdom  
G3 8SJ

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Single-centre

## Study setting(s)

Hospital

## Study type(s)

Not Specified

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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<sub>meas</sub>) and the concentration predicted by the software (C<sub>pred</sub>) 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.

**Secondary outcome measures**

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.

**Overall study start date**

01/11/2008

**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  $\geq 30$  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

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

3 Years

**Sex**

Both

**Target number of participants**

50

**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**

Scotland

United Kingdom

**Study participating centre**

**Department of Anaesthesia**

Glasgow

United Kingdom

G3 8SJ

# Sponsor information

## Organisation

University of Glasgow (UK)

## Sponsor details

c/o Dr Melissa McBride  
Research & Development Academic Coordinator  
University Avenue  
Glasgow  
Scotland  
United Kingdom  
G12 8QQ  
melissa.mcbride@ggc.scot.nhs.uk

## Sponsor type

University/education

## Website

<http://www.gla.ac.uk>

## ROR

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

# Funder(s)

## Funder type

Industry

## Funder Name

Cardinal Health (USA)

# 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