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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	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/08/2008	**Overall study status** Completed	
Last Edited 21/11/2012	**Condition category** Surgery	

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
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 (Cmeas) and the concentration predicted by the software (Cpred) as follows:

PE(%) = [(Cmeas Cpred)/Cpred] x 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 >=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
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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