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Evaluation of a new formulation of Propofol-Lipuro regarding pain on injection in an elective paediatric population

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 18/05/2017	**Condition category** Signs and Symptoms	[ ] 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
N0220173668

Study information

Scientific Title
Evaluation of a new formulation of Propofol-Lipuro regarding pain on injection in an elective paediatric population

Study objectives
Evaluation of a new formulation of Propofol-Lipuro regarding pain on injection in an elective paediatric population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Signs and Symptoms: Pain

Interventions
The effects of the three formulations of this anaesthetic agent will be studied as the patient goes to sleep in the usual way for their operation. We will randomly allocate subjects into three groups prior to receiving the induction agent and injection pain will be evaluated by subjective and objective scoring of pain as they go to sleep. Intravenous canulation will be via a vein on the dorsum of the hand. After a small dose of the drug, they will be asked by the anaesthetist(s) about any soreness in their arm and to rate this as none, mild, moderate or severe. The anaesthetic and operation will proceed in the usual way after this.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Propofol-Lipuro

Primary outcome measure
The outcome measure is reduction of injection pain on induction of anaesthesia with a very commonly-used agent. Although Lipuro has been subject to clinical trials during its development, it has not been compared to other formulations in this way previously.

Secondary outcome measures
Not provided at time of registration

Overall study start date
13/02/2006

Completion date
29/11/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
The sample size in each of the three groups is 30.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
13/02/2006

Date of final enrolment
29/11/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Children's NHS Trust
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Sheffield Children's Hospital NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

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