

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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

29/11/2006

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

England

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)

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

Not provided at time of registration