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Prevention of pain on injection with propofol: Comparison of lignocaine with dilution using 0.9% Sodium Chloride

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 30/03/2020	**Condition category** Signs and Symptoms	

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
N0234131723

Study information

Scientific Title
Prevention of pain on injection with propofol: Comparison of lignocaine with dilution using 0.9% Sodium Chloride

Study objectives
Will the dilution of Fresenius 1% propofol using equal parts of 0.9% Sodium Chloride and 1% Fresenius propofol reduce the incidence of pain on injection in children aged 5 to 10 years?

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory: Pain

Interventions
Children aged 5-10 years (up to approximately 30 kg) will be randomised to either a sample or control group. A single blinded observer will then watch for signs of discomfort on induction of anaesthesia during the injection of propofol. This will be defined as a motor response of the arm, a verbal complaint of pain, a cry and or grimace.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
A reduction in the incidence of pain on injection of Propofol when compared with the most commonly used and effective method in current practice (i.e. the addition of lignocaine - 2 ml 1% per 20 ml propofol).

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/07/2004

Eligibility

Key inclusion criteria
Children aged 5-10 years (up to approximately 30 kg) with American Society of Anesthesiologists (ASA) status 1 or 2 on elective surgical lists.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
10 years

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/11/2003

Date of final enrolment
01/07/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Anaesthetics
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Bristol NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration