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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
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 30/03/2020	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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).

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2003

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

Age group
Child

Lower age limit
5 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Bristol NHS Trust (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