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

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

### Primary study design
Interventional

### Study design
Randomised controlled trial

### 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