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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr A P Madden

#### Contact details

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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