

Comparison of intubating conditions in children after induction of anaesthesia following propofol and suxamethonium with propofol and remifentanyl.

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 11/10/2011	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr A Eissa

Contact details
Anaesthetics, Sheffield Children's NHS Trust
Western Bank
Sheffield
United Kingdom
S10 2TH
+44 (0)114 2717522

Additional identifiers

Protocol serial number
N0220124701

Study information

Scientific Title

Study objectives

Can we successfully perform endotracheal intubation in children using a remifentanil technique and obtain as good conditions as with suxamethonium but without the side effects?

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)

Not Specified

Health condition(s) or problem(s) studied

Surgery: Anaesthesia

Interventions

On arrival in the anaesthetic room, standard monitoring will be applied; peripheral pulse oximeter (S_{po}O₂), electrocardiogram (ECG), non invasive blood pressure (NIBP), and intravenous access sited.

The anaesthetist will open an envelope randomly allocating the patient into one of two groups: Group S to receive Suxamethonium or Group R to receive Remifentanil and will then draw up the appropriate drug for intubation. The child will then be anaesthetised using propofol 3 mg/kg administered over 30 seconds, followed by either Suxamethonium or Remifentanil. A second clinical investigator, unaware of the drug allocation, will enter the anaesthetic room once the patient is asleep and will perform the intubation. Maintenance of anaesthesia will be provided by oxygen/nitrous oxide/Isoflurane gases and hand ventilation at a rate of 6 breaths per minute, monitoring the expired carbon dioxide with capnography. Anaesthesia and surgery will then proceed as normal and on completion the patient will be woken and recovered in the usual manner.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

remifentanil, suxamethonium

Primary outcome(s)

1. Heart rate, blood pressure, oxygen saturation and end tidal carbon dioxide as part of normal anaesthesia. Apnoea time from end of propofol injection to first recognisable breath.

Intubation conditions

2. Intubating condition scores:

Jaw relaxation score: 1 - Relaxed, 2 - Raised Tone, 3 - Rigid

Laryngoscopy score: 1 - Easy, 2 - Difficult, 3 - Impossible

Vocal cords score: 1 - Open, 2 - Moving, 3 - Closed

Coughing score: 1 - None, 2 - Slight, 3 - Severe

Limb movement score: 1 - None, 2 - Slight, 3 - Severe

All score 1 = excellent, some score 2 = good, any score 3 = poor.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/07/2003

Eligibility

Key inclusion criteria

30 patients will be required in each group in the study.

To our knowledge there are no studies of direct comparison between techniques using either suxamethonium or remifentanyl for intubation in the paediatric population. We have found no studies assessing intubating condition, cardiovascular response and apnoea time in children at a lower dose of remifentanyl of 1.25 mcg/kg. This would be possible in children presenting for surgery, who would already require general anaesthesia and intubation and in whom paralysis is not a requirement for surgery itself.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

31/01/2003

Date of final enrolment

31/07/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Anaesthetics, Sheffield Children's NHS Trust

Sheffield

United Kingdom

S10 2TH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Sheffield Children's NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2007		Yes	No