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

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 11/10/2011	**Condition category** Surgery	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
On arrival in the anaesthetic room, standard monitoring will be applied; peripheral pulse oximeter (SpoO2), 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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/01/2003

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 remifentanil 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 remifentanil 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

Age group
Child

Sex
Not Specified

Target number of participants
60

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
England

United Kingdom

Study participating centre
Anaesthetics, Sheffield Children's NHS Trust
Sheffield
United Kingdom
S10 2TH

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
Government

Funder Name
Sheffield Children's NHS Foundation Trust

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

Study outputs

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