Comparison of Sublingual Midazolam and Dexmedetomidine for Premedication in Children.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24728

Source
Nationaal Trial Register

Health condition

Premedication in children scheduled for minor elective procedures such as inguinal hernia repair, circumcision and orchidopexy under general anaesthesia.

Keywords: premedication,children midazolam, dexmedetomidine

Sponsors and support

Primary sponsor: Dept of Anaesthesiology, Pain & Perioperative Medicine
Sir Ganga Ram Hospital, New Delhi ,India
Source(s) of monetary or material Support: Dept of Anaesthesiology, Pain & Perioperative Medicine
Sir Ganga Ram Hospital, New Delhi , India

Intervention

Outcome measures

Primary outcome

1. Behaviour and sedation status of the child during separation from the parent and at induction of anaesthesia;

2. Mask acceptability of the child at induction of anaesthesia;

3. Perioperative changes in heart rate and blood pressure;

4. Behaviour status of the child at time of wake up from anaesthesia.

Secondary outcome

Time to discharge from post-anaesthesia care unit (PACU).

Study description

Background summary

N/A

Study objective

One of the challenges in paediatric anaesthesia is to minimize distress for children in the operating room environment and to facilitate a smooth induction of anaesthesia. Pre-anaesthetic medication reduces the risk of adverse psychological and physiological sequelae of anaesthesia induction in a distressed child. Midazolam is the most commonly used drug for this purpose. Undesirable effects of midazolam such as restlessness, paradoxical reaction and negative postoperative behavioural changes have made it less than an ideal premedication. Dexmedetomidine is a potent, specific and selective ß2-adrenoceptor agonist. It not only produces sedation but also produces anxiolysis, analgesia and decreased activity of sympathetic nervous system. It does not depress respiratory drive. Pharmacological sedation produced by dexmedetomidine mimics natural sleep, making it a promising agent for paediatric sedation.
Because of the unique pharmacological properties of dexmedetomidine we hypothesize that dexmedotomidine may prove to be a better drug for premedication in children as compared to midazolam.

Study design

Time at which the child enters the preoperative suite to the time at which the child is discharged from the post-anaesthesia care unit (also include the duration of anaesthesia).

Intervention

Children will be randomly allocated into two groups:

1. Group I - 0.25 mg/kg midazolam will be given sublingually (drug to be retained in the mouth without spitting or swallowing) by asking the child to place the tip of the tongue to the back of upper teeth. The medication will be given atleast 20 minutes before induction of anaesthesia;

2. Group II- 1.5 µg/kg dexmedetomidine will be given sublingually (drug to be retained in the mouth without spitting or swallowing) by asking the child to place the tip of the tongue to the back of upper teeth. The medication will be given approximately 45 minutes before induction of anaesthesia.

Contacts

Public
Dept of Anaesthesiology, Pain & Perioperative Medicine
Sir Ganga Ram Hospital, New Delhi, India
Deepanjali Pant
New Delhi
India
Scientific
Dept of Anaesthesiology, Pain & Perioperative Medicine
Sir Ganga Ram Hospital, New Delhi, India
Deepanjali Pant
New Delhi
India

Eligibility criteria

Inclusion criteria

1. Children with ASA physical status I or II;

2. Age between 1 and 12 years;

3. Children undergoing elective inguinall hernia repair, orchidopexy or circumcision, under general anaesthesia and caudal block.

Exclusion criteria

1. Known allergy or hypersensitive reaction to midazolam or dexmedetomidine;

2. Liver or renal dysfunction;

3. Cardiac arrhythmia or congenital heart disease;

4. Mental retardation;

5. Use of enzyme inducing medication e.g. phenobarbitone;

6. Upper respiratory tract infection.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-12-2010
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2531
NTR-old	NTR2649
Other	: EC 09/10/171
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A