

# Comparison of Sublingual Midazolam and Dexmedetomidine for Premedication in Children.

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	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  $\beta_2$ -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 dexmedetomidine 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

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## Eligibility criteria

### Inclusion criteria

1. Children with ASA physical status I or II;
2. Age between 1 and 12 years;
3. Children undergoing elective inguinal 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