Comparison of Sublingual Midazolam and Dexmedetomidine for Premedication in Children.

Gepubliceerd: 11-12-2010 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24728

Bron
NTR

Aandoening

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

Keywords: premedication,children midazolam, dexmedetomidine

Ondersteuning

Primaire sponsor: Dept of Anaesthesiology, Pain & Perioperative Medicine
Sir Ganga Ram Hospital, New Delhi ,India
Overige ondersteuning: Dept of Anaesthesiology, Pain & Perioperative Medicine
Sir Ganga Ram Hospital, New Delhi , India

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-12-2010
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A