Endoscopy with EEG-control in children between 1 and 12 years

Gepubliceerd: 06-06-2016 Laatst bijgewerkt: 15-05-2024

Narcotrend Index (Depth of Hypnosis Index, derrived from EEG) guided application of propofol may result in faster emergence after procedural sedation for gastrointestinal endoscopy in paediatric patients aged between 1 and 12 years

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23511

Bron
Nationaal Trial Register

Verkorte titel
NI-PPS 2

Aandoening

Sedation, Propofol, Children, Endoscopy, EEG

Ondersteuning

Primaire sponsor: Erasmus University Medical Center, Sophia Children's Hospital, Department of Anaesthesia
Rotterdam, The Netherlands
Overige ondersteuning: Erasmus University Medical Center, Sophia Children's Hospital, Department of Anaesthesia
Rotterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is the effect of electroencephalographic Narcotrend Index (NI) monitoring on the speed of recovery from Procedural Sedation for paediatric gastrointestinal endoscopy.

Toelichting onderzoek

Doel van het onderzoek

Narcotrend Index (Depth of Hypnosis Index, derrived from EEG) guided application of propofol may result in faster emergence after procedural sedation for gastrointestinal endoscopy in paediatric patients aged between 1 and 12 years

Onderzoeksopzet

Dataanalysis after completion of inclusion

Onderzoeksproduct en/of interventie

Patients are prospectively randomised to two groups.
In the intervention group the application of propofol to provide procedural sedation for gastrointestinal endoscopy is guided by the Narcotrend Index of hypnotic depth. In the control group dosing of propofol is based on clinical observations of depth of hypnosis.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Written informed consent of patients and their parents/legal representatives

Age ≥1 and <12 years

Bodyweight >5 and ≥60 kg (limitation of the paediatric pharmocokinetic model)

Gastrointestinal endoscopy

Eligibility for procedural sedation

Ability of the patient to communicate in Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Primary exclusion criteria:

Withdrawal of informed consent

Chronic exposure (more than one day) to psychotropic drugs and/or opioids

Known allergy/intolerance for propofol and/or remifentanil

Anticipated difficult airway

Child not eligible for procedural sedation, need for general anaesthesia

Patient and/or parents unable to communicate in Dutch

Secondary exclusion criteria:

Unexpected procedural events requiring endotracheal intubation

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-06-2016
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-06-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43430
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5473
NTR-old	NTR5890
CCMO	NL56591.078.16
OMON	NL-OMON43430

Resultaten