Endoscopy with EEG-contol

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28327

Source
Nationaal Trial Register

Brief title
NI-PPS

Health condition

Sedation
Propofol
Children
Gastrointestinal endoscopy
Depth of Anaesthesia Monitoring
EEG

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Sophia Children's Hospital
Rotterdam
The Netherlands
Source(s) of monetary or material Support: Erasmus University Medical Center
Grant 'Doelmatigheidsonderzoek'

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Cumulative anaesthetic drug consumption

Total time from discontinuation of anaesthetic drug delivery until discharge from the post anaesthesia care unit.

Posthoc intergroup comparison of hypnotic depth as measured by Narcotrend

Incidence of recall of events during the procedure (awareness)

Assessment of endoscopy conditions (by paediatric gastroenterologist)

Adverse events

Economic Analysis (Cost minimization analysis, CMA)

Study description

Study objective

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

Study design

Dataanalysis after completion of inclusion

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

Written informed consent of patients and their parents/legal representatives

Age ¡Ý12 and <17 years

Bodyweight ¡Ü 60 kg (limitation of the paediatric pharmocokinetic model)

Gastrointestinal endoscopy

Eligibility for procedural sedation

Ability of the patient to communicate in Dutch

Exclusion criteria

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 inhalation induction and general anaesthesia

Patient and/or parents unable to communicate in Dutch

Secondary exclusion criteria:

Unexpected need for inhalation induction of general anaesthesia due to major difficulties to obtain intravenous access.

Unexpected procedural events requiring endotracheal intubation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2015
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	12-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38989
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4379
NTR-old	NTR4593
CCMO	NL44307.078.13
OMON	NL-OMON38989

Study results