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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23511

Source
Nationaal Trial Register

Brief title
NI-PPS 2

Health condition

Sedation, Propofol, Children, Endoscopy, EEG

Sponsors and support

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

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

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 aged between 1 and 12 years

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 ≥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

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 general anaesthesia

Patient and/or parents unable to communicate in Dutch

Secondary exclusion criteria:

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:	Recruiting
Start date (anticipated):	07-06-2016
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43430
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results