The influence of electroencephalographic Narcotrend Index*- guidance of propofol administration on recovery from procedural sedation for gastrointestinal endoscopy in paediatric patients

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To evaluate the impact of electroencephalographic Narcotrend* Index (NI) monitoring on the speed of emergence and recovery from PPS for PGE.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38989

Source
ToetsingOnline

Brief title
NI-PPS

Condition

- Other condition

Synonym
not applicable

Health condition

onderzoek tijdens procedurele sedatie bij kinderen, niet gerelateerd aan specifieke aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, EEG, Gastrointestinal Endoscopy, Procedural Sedation

Outcome measures

Primary outcome

The primary objective of this study is the effect of NI monitoring on the speed of recovery from procedural sedation for paediatric gastrointestinal endoscopy. Speed of recovery is defined as the time interval between the end of propofol application and the moment when discharge criteria from the operating room are met.

Secondary outcome

Secondary Objective(s):

• Cumulative propofol consumption

• Total time from discontinuation of propofol delivery until discharge from the post anaesthesia care unit

• Posthoc intergroup comparison of hypnotic depth as measured by Narcotrend

• Detection of possible recall of events during the procedure (awareness)

• Assessment of endoscopy conditions (by paediatric gastroenterologist)

• Adverse events

• Economic Analysis (Cost minimization analysis, CMA)

Study description

Background summary

EEG-based depth of hypnosis (DoH) monitoring during paediatric procedural sedation (PPS) may result in a faster recovery after the procedure, compared to a standard PPS regimen. From a scientific point of view the key question is whether the application of DoH monitoring results in advantages for both the patient (probably less exposure to propofol and faster recovery) and the health care providers (enhanced workflow on the operation room) are big enough to spend some extra money for the DoH-monitoring devices and disposables. This question will be approached in a series of three clinical trials. Part one of the whole project is this trial especially designed for the setting of PPS during paediatric gastrointestinal endoscopy (PGE).

Study objective

To evaluate the impact of electroencephalographic Narcotrend* Index (NI) monitoring on the speed of emergence and recovery from PPS for PGE.

Study design

Single centre, prospective randomised, double-blind, controlled trial.

Intervention

In patients in the intervention group the anaesthetic propofol will be titrated according to depth of hypnosis (DoH) data provided by the Narcotrend* with a Narcotrend Index (NI) target range of 65±5. In patients in the control group, the conduct of PPS is based on commonly applied conventional clinical surrogate parameters of DoH, such as heart rate, blood pressure and patient movement.

Study burden and risks

In patients in the intervention group PPS will be administered on the basis of objective measures of anaesthetic depth, the NI values. We expect a significantly faster emergence than with the conventional PPS approach. The Narcotrend has been validated for use in paediatric patients. There are thus no additional risk factors apart from those, which are inherent with gastrointestinal endoscopy under procedural sedation. A non-invasive therapeutical intervention (NI-based conduct of PPS) should result in the advantage of faster recovery, without any additional risk factor.
Patients in the control group will receive standard treatment, that is delivery of propofol based on the judgement of clinical surrogate parameters of DoH.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

• Written informed consent of patients and their parents/legal representatives
• Age >=12 <17 years
• Bodyweight <= 60 kg
• 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Propofol 10 mg/ml MCT/LCT Fresenius emulsie voor injectie of infusie
Generic name:	Propofol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-07-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-07-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28327
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-02122-23-NL
CCMO	NL44307.078.13
OMON	NL-OMON28327