aepEX™ Depth of Anaesthesia Monitoring in Children.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27038

Source
NTR

Brief title
aepEX paediatric

Health condition

Depth of Anaesthesia
Auditory Evoked Potentials
Paediatric Anaesthesia
BIS monitor
aepEX

Sponsors and support

Primary sponsor: Erasmus University Medical Center, Rotterdam
Dep. of Anaesthesia
Paediatric Anaesthesia Unit - Sophia Children's Hospital
Source(s) of monetary or material Support: Stichting Coolsingel, Rotterdam
Erasmus University Medical Center, Rotterdam
Dep. of Anaesthesia

Intervention

Outcome measures

Primary outcome

The performance of the aepEX™ as a measure of DoH in paediatric patients (1-18 years old), anaesthetised with propofol, sevoflurane or desflurane. The accuracy of the aepEX™ will be expressed in Pk-values.

Secondary outcome

The effects of different propofol concentrations, (applied by Target Controlled Infusion), sevoflurane and desflurane concentrations on the aepEX, the University of Michigan Sedation Scale (UMSS), BIS and hemodynamic variables.

MLAEP latencies and amplitudes will be extracted from the raw-MLAEP waveforms and linked to propofol plasma, sevoflurane and desflurane concentrations and the UMSS.

Study description

Background summary

N/A

Study objective

N/A

Study design

During anaesthesia, including induction and emergence.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 1-18 years;

2. General anaesthesia;

3. Planned elective surgery.

Exclusion criteria

1. Significant hearing impairment;

2. Intake of drugs affecting the EEG;

3. Having a disorder affecting the EEG;

4. Allergy for propofol, remifentanil, sevoflurane and/or desflurane;

5. Planned PICU admission post-operatively with ventilatory support and sedation;

6. Unable to obtain written informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2011
Enrollment:	225
Type:	Actual

Ethics review

Positive opinion

Date:	12-07-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2841

Register	ID
NTR-old	NTR2983
Other	MEC Erasmus MC : 2011-104
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Cheung YM, Scoones GP, Hoeks SE, Stolker RJ, Weber F. Evaluation of the aepEX monitor of hypnotic depth in pediatric patients receiving propofol-remifentanil anesthesia. Paediatric anaesthesia. 2013;23(10):891-7.

Cheung YM, Scoones GP, Stolker RJ, Weber F. Evaluation of the auditory evoked potentials derived aepEX() as a measure of hypnotic depth in pediatric patients receiving sevoflurane-remifentanil anesthesia. Paediatric anaesthesia. 2014;24(7):760-5.