The influence of electroencephalographic density spectral array guidance of sevoflurane administration on recovery from general anaesthesia in children between 6 months and 12 years.

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To evaluate the influence of DSA monitoring, provided by the NarcotrendTM monitor, on the speed of emergence and recovery from GA.

Ethical review	Approved WMO
Status	Completed
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56659

Source
ToetsingOnline

Brief title
The effect of DSA on recovery of anaesthesia in children

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
n.v.t.

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: electroencephalography, general anesthesia, pediatrics, recovery

Outcome measures

Primary outcome

the influence of density spectral array monitoring with the Narcotrend monitor

on the speed of emergence from general anaesthesia with sevoflurane. The speed

of emergence is defined as the time interval between the end of hypnotic drug

application and the moment when discharge criteria from the operating room are

met (defined as a Steward score >= 3).

Secondary outcome

Total time from discontinuation of anaesthetic drug delivery until discharge

from the post anaesthesia care unit.

The difference in intra-operative blood pressure between the intervention group

and the control group.

Differences of depth of hypnosis during the procedure, as measured by the

Narcotrend monitorTM.

The incidence of postoperative delirium by the Cornell Assessment of

Postoperative Delirium (CAPD) score

Incidence of recall of events during the procedure (awareness)

Adverse events

Study description

Background summary

Electroencephalographic density spectral array (DSA) is a three dimensional method to display electroencephalogram (EEG) signals consisting of the EEG frequency (y-axis), the power of the EEG signal (colour-coded to be integrated into a two dimensional plot) and the development of the EEG power spectrum over time (x-axis). DSA is routinely used to measure depth of hypnosis (DoH) by a part of the staff members in our department. When DSA is used, dose adjustments of sevoflurane will be made based on monitoring depth of anaesthesia. However, most of our colleague do not use DSA. Dose adjustment is then based on (subjective) clinical surrogate parameters, or in general mostly based on a minimal alveolar concentration of the anaesthetic gas that is used. Electroencephalographic DSA monitoring provides continuous objective information on DoH and should result in a faster speed of emergence and recovery from general anaesthesia (GA). This will be addressed in a randomised controlled trial.

Study objective

To evaluate the influence of DSA monitoring, provided by the NarcotrendTM monitor, on the speed of emergence and recovery from GA.

Study design

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

Intervention

In patients randomised to the intervention group of the trial, the anaesthetic agent sevoflurane will be titrated according to the typical DSA pattern for GA with sevoflurane, provided by the NarcotrendTM.
In patients randomised to the control group, sevoflurane will be titrated according to a Minimal Alveolar Concentration (MAC) of 0.9 respectively an end tidal sevoflurane concentration of 2.3% based on standard practice in our paediatric anaesthesia department.

Study burden and risks

In patients randomised to the intervention group, the anaesthetic agent sevoflurane will be administered on the basis of objective measures of anaesthetic depth, the typical DSA pattern for GA. We expect a significantly faster speed of emergence and recovery based on clinical experiences with the use of DSA. The NarcotrendTM monitor is validated for use in paediatric patients. There are thus no additional risk factors apart from those, which are inherent with general anaesthesia. Patient randomised to the control group will receive standard treatment, that is delivery of sevoflurane based on a MAC of 0.9 respectively an end tidal sevoflurane concentration of 2.3%.

A non-invasive therapeutical intervention (DSA based conduct of GA) should result in the advantage of faster recovery, without any additional risk factor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Written informed consent of the parents/legal representatives
Age > 6 months and < 12 years
Surgical procedure requiring general anaesthesia supplemented with caudal analgesia
Ability of the parents or legal guardians to communicate in Dutch

Exclusion criteria

Withdrawal of informed consent
(Chronic) use of drugs influencing the electroencephalogram
Use of premedication
Known intolerance for sevoflurane
Parents/legal guardians unable to communicate in Dutch

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-09-2022
Enrollment:	112
Type:	Actual

Medical products/devices used

Generic name:	Narcotrend-Compact M
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-07-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL80282.078.22