'The frequency of behaviour disturbances after different concentration of anaesthetic gases (Sevoflurane) for anaesthesia during M.R.I. examination in children.

No registrations found.

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

Summary

ID

NL-OMON21231

Source
NTR

Brief title
EDSEV

Health condition

Emergence delirium (ED) is described as a mental disorder during recovery from general anaesthesia. After the introduction of new inhalation anaesthetics such as Sevoflurane, this phenomenon again gained prominence. The specific cause is unknown. Anaesthesia, surgery and patient related factors are part of the possible explanations.

Sponsors and support

Primary sponsor: Department of Anaesthesia, Erasmus University Medical Centre Rotterdam, Sophia Children□fs Hospital, Rotterdam
Dr. Molewaterplein 60
3015 GJ Netherlands
Source(s) of monetary or material Support: Department of Anaesthesia, Erasmus University Medical Centre Rotterdam, Sophia Children□fs Hospital, Rotterdam

Dr. Molewaterplein 60
3015 GJ Netherlands

Intervention

Outcome measures

Primary outcome

The primary endpoints are the maximum scores on the Pediatric Anesthesia Emergence Delirium Scale (PAED) until 1 hour after having stopped the administration of the anaesthetic. We consider a score of >12 on the PAED scale as cut-off for the presence or absence of ED.

Secondary outcome

1. The secondary endpoints are the time between terminating the administration and the removal of the laryngeal mask airway and the time of reaction (responsiveness) to light or gentle tactile stimulation;

2. Are parents and childrens anxiety at induction, as well as their behaviour, a predictive value for the appearance of ED?

Study description

Background summary

Rationale:

'Emergence delirium' (ED) is described as a mental disorder during recovery from general anaesthesia. After the introduction of new inhalation anaesthetics such as Sevoflurane, this phenomenon again gained prominence. The specific cause is unknown. Anaesthesia, surgery and patient related factors are part of the possible explanations.

Objective of the research:

The primary research inquiry being raised concerns anaesthesia related causes:
Is it possible that adapting an amount of Sevoflurane, from 1 MAC (minimum alveolar concentration) (2,5 vol%) to ½ MAC (1,25 vol%) in an MRI scan can reduce the frequency and gravity of 'emergence delirium'?

The secondary research inquiry being raised concerns patient related causes:

Are parents' and children's anxiety at induction, as well as their behaviour, a predictive value for the appearance of 'ED'?

Study design:

Randomised double-blinded research on 2 groups of children ranging from 1.5 to 5 years old.
Study population: 110 children who have to undergo an MRI scan for diagnostic reasons.
Intervention: during the diagnostic research 1 MAC (2,5 vol%) or ½ MAC (1,25 vol%) Sevoflurane is administered.

Main study parameters/endpoints:

The primary endpoints are the maximum scores on the 'Pediatric Anesthesia Emergence Delirium Scale' (PAED) until 1 hour after having stopped the administration of the anaesthetic. We consider a score of >12 on the PAED scale as cut-off for the presence or absence of ED. The secondary endpoints are the time between terminating the administration and the removal of the laryngeal mask airway and the time of reaction ('responsiveness') to light or gentle tactile stimulation.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

This research does not lead to an increased risk. The risk is similar to the one for general anaesthesia. The accompanying parent will be presented with two short questionnaires (duration maximum 15 min.). A subpopulation of young preschool children seems to be most vulnerable to 'emergence delirium'. With this research our anaesthesia policy is thus adapted to prevent 'ED'. Even though there is no standard technique for the admission of anaesthesia during a MRI scan, the administering of a Sevoflurane concentration around 1 MAC is considered most common. A deviation from this common rule, the administering of a lower concentration of Sevoflurane to avoid ED, is therefore a therapeutic intervention.

Study objective

1. The primary research inquiry being raised concerns anaesthesia related causes:
Is it possible that adapting an amount of Sevoflurane, from 1 MAC (minimum alveolar concentration) (2,5 vol%) to ½ MAC (1,25 vol%) in an MRI scan can reduce the frequency and gravity of emergence delirium?

2. The secondary research inquiry being raised concerns patient related causes:

Are parents and childrens anxiety at induction, as well as their behaviour, a predictive value

for the appearance of ED?

Study design

During the first hour after the awakening constant observation is done and the behaviour of the child is assessed in the recovery room by using the Pediatric Anesthesia Emergence Delirium (PAED) scale. A total sum of > 12 on the scale creates is chosen as distinction between presence or absence of clinical relevant agitation.

The anxiety level and the need for information of the accompanying parent is measured by using the Amsterdam Preoperative Anxiety and Information Scale (APAIS).

The behavior of the child is measured by using the CBLC/11/2-5, Child Behavior Checklist for Ages 11/2-5).

At admission in the day case hospital the anxiety level is measured for a first time by using the modified Yale Preoperative Anxiety Scale (m-YPAS) and a second time at induction.

We use the University of Michigan Sedation Scale (UMSS scale) to determine when we apply the first measurement of the Pediatric Anesthesia Emergence Delerium (PAED) scale and chose a score of 3 as a point of reference.

Intervention

during the diagnostic research 1 MAC (2,5 vol%) or ½ MAC (1,25 vol%) Sevoflurane is administered.

Contacts

Public
Erasmus MC - Sophia
Dr. Molewaterplein 60
F. Weber
Rotterdam 3015 GJ
The Netherlands
+31 (0)10 7040704
Scientific
Erasmus MC - Sophia
Dr. Molewaterplein 60
F. Weber
Rotterdam 3015 GJ
The Netherlands
+31 (0)10 7040704

Eligibility criteria

Inclusion criteria

1. Age between 1,5-5 years;

2. Written permission (informed consent);

3. No premedication;

4. Children who have to undergo a diagnostic MRI scan;

5. ASA status 1-2;

6. Parents who speak Dutch;

7. Parent present at induction.

Exclusion criteria

1. Cognitive or emotional development disorder (with exception of attention deficit hyperactivity disorder (ADHD));

2. Use of active ingredients (AI) which influence the central nervous system (anticonvulsants);

3. Those who run the risk of developing malignant hyperthermia;

4. Hypersensitivity to the inhalation anaesthetic Sevoflurane and to propofol;

5. Need for premedication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2011
Enrollment:	110
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-09-2011
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	NL2912
NTR-old	NTR3058
Other	METC ErasmusMC : MEC-2011-069

Study results

Summary results
N/A