# The influence of MAC values and behaviour of a child on emergence delirium after sevoflurane anesthesia

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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 * MAC (1,25 vol%) in an MRI scan can reduce the frequency…

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34222

**Source**
ToetsingOnline

**Brief title**
EDSEV/version 3.0 May 2010

### Condition

- Other condition
- Deliria (incl confusion)

**Synonym**
emergence delirium

**Health condition**

postoperatieve gedragsstoornissen na sevoflurane anesthesie

**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:** Emergence Delirium, Sevoflurane

## Outcome measures

### Primary outcome

Primary research question:

Is it possible that adapting the amount of sevoflurane, from 1 MAC (2,5 vol%)

to * MAC (1,25 vol%) in an MRI scan can reduce the frequency and gravity of ED?

### Secondary outcome

Secondary research questions:

1.Do the anxiety of the parents (measured by the APAIS), the anxiety of the

child at induction (measured by the m-YPAS) and the behaviour (measured by the

CBCL 11/2-5) constitute a predictive value for the appearance of ED (measured

with the PAED scale)?

2.In case significant ED appears, can this lead to an increase of behavioural

disorders (measured by the PHBQ) at 1 day, 1 week en 2 weeks after

intervention?

# Study description

### Background summary

*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.

## Study objective

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 * 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*?
In case a significant *ED* appears, can this lead to an increase of behavioural disorders at 1 day, 1 week and 2 weeks after intervention?

## Study design

Randomised double-blinded study in 40 children who have to undergo a MRI scan for diagnostic reasons under general anaesthesia in the Sophia Children*s Hospital Erasmus MC Rotterdam. After randomisation the children are divided in two groups (stratification according to age).
Group A sevoflurane 1 MAC (2,5 vol.%)
Group B sevoflurane 0,5 MAC (1,25 vol.%)
Further division in age group
1. >1,5 year old < 4 years old 2 x 10 children
2. >4 years old < 6 years old 2 x 10 children
*

## Intervention

randomization into two groups:
Group A sevoflurane 1 MAC (2,5 vol.%)
Group B sevoflurane 0,5 MAC (1,25 vol.%)

## Study burden and risks

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.). On day 1, day 7 en 2 weeks after the anaesthesia there will be an assessment over the phone concerning the postoperative behaviour of the child by means of a standard questionnaire.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

age between 1,5-6 years
children scheduled for MRI scan onder general anesthesia
no premedication
ASA status 1-2
parents who speak Dutch
parents present during anesthesia induction
written informed consent

## Exclusion criteria

Cognitive or emotional developmental disorder, with exception of attention deficite hyperactivity disorder.

Use of active ingredients which influence the central nervous system (anticonvulsants)
Risk of malignant hyperthermia
Hypersensitivity to sevoflurane or propofol
Need for premedication

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |
| Primary purpose: | Other |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 31-01-2011 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Generic name: | Sevoflurane (volatile anesthetic) |
| Registration: | Yes - NL intended use |

# Ethics review

Approved WMO

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|---|---|
| Date: | 27-01-2011 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

# 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 |
|---|---|
| EudraCT | EUCTR2010-019420-31-NL |
| CCMO | NL32082.000.10 |