# The influence of preoperative emotional and behavioral function of children on postoperative behavior: Child Behavior Checklist ANESthesia Emergence Delirium

Recruitment status	<ul><li>Prospectively registered</li></ul>
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	[X] Results
Condition category	Individual participant data
	No longer recruiting  Overall study status  Completed

## Plain English summary of protocol

Background and study aims

We are carrying out a study in children looking at their confusion when they wake up from anesthesia for dental surgery.

## Who can participate?

All healthy children between 18 months and 2 years of age who have to undergo dental surgery needing anesthesia can take part.

## What does the study involve?

Parents are asked to fill out some questionnaires (this takes 20 minutes) and their child will be observed by a research nurse who scores their child on anxiety before anesthesia and on confusion when he/she wakes up from anesthesia.

What are the possible benefits and risks of participating?

Apart from more attention to their child, there is no direct benefit in participating in the study, neither is there any risk involved.

Where is the study run from?

Queen Paola Childrens Hospital, Antwerp (Belgium).

When is the study starting and how long is it expected to run for? The study started in April 2014 and is expected to run until April 2015.

Who is funding the study?

Department of Anesthesia, ZNA Middelheim Queen Paola Childrens Hospital (Belgium).

Who is the main contact?

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# Contact information

## Type(s)

Scientific

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# Additional identifiers

## Protocol serial number

B009201420027

# Study information

#### Scientific Title

The influence of preoperative emotional and behavioral functioning of children between 1.5 and 12 on postoperative emergence delirium (ED) after dental surgery in day care

## Acronym

**CBCL-ANES-ED** 

## **Study objectives**

Primary hypothesis:

What is the influence of emotional and behavioral functioning (externalising/internalising) 6 months prior to surgery of a child between 1.5 and 12 years old undergoing dental surgery on ED at awakening?

Using:

- 1. The Pediatric Anesthesia Emergence Delirium Scale (PAED)
- 2. A short Additional Structured Behavior Observation (ASBO)

## Secondary hypothesis:

- 1. What is the influence of emotional and behavioral functioning (externalising/internalising) 6 months prior to surgery of a child between 1.5 and 12 years old undergoing dental surgery on postoperative pain at awakening?
- 2. What is the relationship between the state anxiety of the child measured/observed with the modified Yale Preoperative Anxiety Scale (mYPAS), the preoperative anxiety indicated by the child itself (group 612 years old) using a Visual Analogue Scale (VASanxiety-child-6-12) on the one hand and ED on the other?

- 3. What is the influence of the state and trait anxiety of the accompanying parent measured on the day of admission, in the operating theater and after leaving the operating theater with Spielbergers State-Trait Anxiety Inventory (STAI) on postoperative ED?
- 4. Do parents of children undergoing dental surgery experience more dental fear as measured with the modified Dental Anxiety Scale (mDAS) compared to normative data?
- 5. What is the relationship between ED (measured with the PAED scale and the short ASBO) and the postoperative pain scores determined by a nurse using the Face (F), Legs (L), Activity (A), Cry (C), Consolability (C) Scale (FLACC scale) on the one hand and pain as measured by the parents using a Visual Analogue Scale (VASparent-child-pain-in-hospital) and by the child itself (≥ 6 years old) using a face scale Faces Pain Scale Revised (FPS-R) on the other hand?

## Additional questions:

1. Research reliability and validity of the translated anxiety observation scale modified Yale Preoperative Anxiety Scale (mYPAS).

To determine:

- 1.1. Construct validity
- 1.2. Concurrent validity
- 1.3. Interrater reliability
- 1.4. Test-retest reliability

To be executed on a limited random sample out of a total cohort 60/160 children (40%).

- 2. Pediatric Anesthesia Emergence Delirium Scale (PAED) and the Additional Structured Behavior Observation (ASBO)
- 2.1. Compare both observation scales and recode the PAED scale with sensitivity and specificity analysis
- 2.2. Determine the interrater reliability
- 2.3. Measure the internal consistency
- 2.4. To be executed on the results of the total cohort
- 2.5. To be executed on a limited random sample out of the total cohort 60/160 children (40%). Concerning content it is important to have the observation done by a second rater so that in this way the reliability and quality of the measurement can be determined. Academic journals demand more and more measurement reliability of the coders. Therefore it is necessary in this research to specifically check the reliability of the observations.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Institutional Review Board (nr. 009; OG 031), 12/02/2014, EC approval number 4343

## Study design

Prospective single-institution cohort study

## Primary study design

Observational

## Study type(s)

Other

## Health condition(s) or problem(s) studied

Maladaptive perioperative behavior in children

#### **Interventions**

This trial is an observation of 160 children who undergo dental surgery under anesthesia. Parents are asked to fill in a questionnaire on emotional and behavioral functioning of their child. A research nurse will make observations on anxiety at three time points:

- 1. On admission in the day care unit
- 2. When entering the operating theatre
- 3. At induction of anesthesia

The research nurse will also perform additional observations of emergence delirium (four time points during 20 min = T1 at 5 min, T2 at 10 min, T3 at 15 min, T4 at 20 min) when the child wakes up after anesthesia (additionally followed by two pain score observations at 1 hour and 2 hours postoperative by the research nurse). The total duration of observation takes approximately 6 hours for each child (day care surgery). There is no further follow-up at home, only intrahospital observations during admission for their surgery.

## Intervention Type

Procedure/Surgery

#### Phase

Not Applicable

## Primary outcome(s)

The scores on the Pediatric Anesthesia Emergence Delirium Scale (PAED) scale during 20 minutes postoperative and parallel to this the item score on the Additional Structured Behavior Observation (ASBO)

## Key secondary outcome(s))

Postoperative pain scores concerning the child:

- 1. Just after waking up from anesthesia together with emergence delirium observations (four time points during 20 min every 5 min) an additional pain observation is done by using an observational pain measuring tool (FLACCnurse). When leaving the Post Operative Care Unit (PACU) two additional pain measurements are done again using a FLACCnurse scale (T1: 1 hour after leaving the PACU and T2: 2 hours after leaving the PACU).
- 2. Also at these same time points the parents are asked to assess their childs pain by using a Visual Analogue Scale (VAS).
- 3. If the child is older than 6 years of age the child is asked to assess its pain by itself using a Faces Pain Scale revised (FPS-R) (same time points as the parental assessment).

## Taking note of:

- 1. The total intake of analgesics
- 2. Postoperative nausea and vomiting

# Completion date

01/04/2015

# **Eligibility**

Key inclusion criteria

- 1. Age from 1.5 to 12 years old
- 2. Intervention: dental surgery anesthesia
- 3. Information and consent forms of the parents
- 4. Accompanying parent present at induction
- 5. Parents who speak and understand Dutch
- 6. No premedication (the norm in Queen Paola Childrens Hospital)

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

1.5 years

## Upper age limit

12 years

#### Sex

All

## Key exclusion criteria

- 1. Known mental/cognitive retardation
- 2. American Society Anesthesiologists ASA physical status I and II (attachment 15)
- 3. Children with objectified obstructive sleep apnea syndrome
- 4. Children with BMI > 25
- 5. Allergic reaction to sevoflurane and/or risk of malign hyperthermia

## Secondary exclusion criteria:

- 1. When parent or child no longer wish to participate
- 2. When a life-threatening situation occurs during the procedure (e.g., asystole)

## Date of first enrolment

01/04/2014

## Date of final enrolment

01/04/2015

# Locations

## Countries of recruitment

Belgium

## Study participating centre

## Lindendreef 1

Antwerp Belgium 2020

# Sponsor information

# Organisation

ZNA Middelheim - Queen Paola Childrens Hospital (Belgium)

## **ROR**

https://ror.org/01z5jvj74

# Funder(s)

## Funder type

Hospital/treatment centre

## **Funder Name**

ZNA Middelheim - Queen Paola Children's Hospital (Belgium)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	preliminary results	01/02/2015	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes