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

Submission date
30/03/2014

Recruitment status
No longer recruiting

Registration date
19/05/2014

Overall study status
Completed

Last Edited
07/02/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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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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

Primary study design
Observational

Study design
Prospective single-institution cohort study

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