DE INVLOED VAN PREOPERATIEF EMOTIONEEL EN GEDRAGSMATIG FUNCTIONEREN VAN KINDEREN TUSSEN 1.5 EN 5 JAAR OP POSTOPERATIEVE PIJN NA ADENOTONSILLECTOMIE IN DAGZIEKENHUIS.

EEN PROSPECTIEF COHORT ONDERZOEK.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26084

Source
NTR

Brief title
CBCL - A/AT- POK 1.5-5

Health condition

child, postoperative pain after tonsillectomy/adenotonsillectomy
kinderen, postopertieve pijn

Sponsors and support

Primary sponsor: Dienst Anesthesie & Reanimatie
Lindendreef 1

2020 Antwerpen
Source(s) of monetary or material Support: institutional means
fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. The scores of the Parents' Postoperative Pain Measure (PPMPaccompanying parent) during three days postoperative;

2. Assessment of the pain scores by the child and the parent by means of a Visual Analogue Scale (VAS parent-child-pain-at home) for the accompanying parent during three days postoperative.

Secondary outcome

1. The pain scores of the child and the accompanying parent in the postoperative day care and by means of a Visual Analogue Scale (VASparent-child-pain-in-hospital) for the parent;

2. The pain scores measured by the FLACCnurse;

3. The total administration of analgesics at home (as noted in the diary) during three days and at day ten postoperative.

Study description

Background summary

N/A

Study objective

The purpose of this research is to acquire a better understanding of the pain experience and the recovery of children between 1.5 and 5 years old who underwent a tonsillectomy/adenotonsillectomy.

Primary research question:

What is the influence of emotional and behavioral functioning (externalizing/internalizing) six months prior to surgery of a child between 1.5 and 5 years old undergoing a tonsillectomy/adenotonsillectomy on the measured postoperative pain scores by the parents and by the child itself?

1. Using the Parents' Postoperative Pain Measure (PPPMaccompanying-parent);

2. Using a Visual Analogue Scale (VASparent-pain-child-at-home) for the parent.

Secondary research questions:

1. What is the relation between the preoperative anxiety of the child and the parent by means of a Visual Analogue Scale (VASanxiety-parent-preoperative) and the postoperative pain scores in day care (VASparent-child-pain-in hospital) and the scores at home during three days (VASparent-child-pain-at-home)?

2. What is the influence of the difference between high versus low pain scores of children (with a cut-off ≥ 4 VASparent-child-pain-at-home) on the administration of analgesics?

Additional questions:

Furthermore this research focuses on the following additional questions:

1. What is the correlation between VASparent-child-pain-at-home on the one hand and the PPPMaccompanying-parent during three days postoperative on the other hand?

2. What is the Intraclass Correlation Coefficient (ICC) between pain measured by the both parents by means of a VASparent-child-pain-at-home during three days postoperative?

3. What is the ICC between the PPPM measurements of both parents during three days postoperative?

4. What is the influence of the state and trait anxiety of the accompanying parent measured with the Spielberger's State-Trait Anxiety Inventory (STAI) on the postoperative pain measurement and the administration of analgesics of the child?

5. What is the influence of the need for information (information seeking versus information avoiding behavior), of the accompanying parent measured with the Amsterdam Preoperative Anxiety Information Scale (APAIS) on the postoperative pain measurement and the administration of analgesics of the child?

6. What is the correlation between VASparent-child-pain-in-hospital on the day of surgery and the pain assessments on the Face, Legs, Activity, Cry, Consolability Scale (FLACC) measured

by an independent nurse (FLACCnurse) in the postoperative section of the day care?

7. What is the relation between preoperative externalizing/internalizing problems measured with the Child Behavior Checklist (CBCL 1.5-5), the anxiety of the child at induction measured with the modified Yale Preoperative Anxiety Scale (T3mYPAS) and emergence delirium at awakening from anesthesia measured with the Pediatric Anesthesia Emergence Delirium scale (PAEDsum scores at T1-T2-T3)?

8. Identifying sleeping problems of the child (falling asleep, waking up, nightmares) during three days postoperative by using a few specific questions concerning sleeping disorders of the Post Hospitalisation Behavioral Questionnaire (PHBQ).

9. Validation of translated behavior observation instruments (PPPM, FLACC, mYPAS, a few questions of the PHBQ).

Study design

Day of surgery, three days postoperative and day ten postoperative.

Intervention

Observation - no intervention.

Contacts

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Eligibility criteria

Inclusion criteria

1. From 1.5 to and including 5 years old;

2. Surgery: tonsillectomy or combined adenotonsillectomy;

3. Information and consent forms and assent form explained to the child;

4. Accompanying parent present at induction;

5. Parents who speak and understand Dutch;

6. No premedication (the norm in Queen Paola Children’s Hospital).

Exclusion criteria

1. Known mental/cognitive retardation;

2. American Society Anesthesiologists ASA physical status > II;

3. Children with objectified obstructive sleep apnea syndrome;

4. Children with BMI > 25;

5. Allergic reaction to sevoflurane and/or risk of malign hyperthermia.

Secundary exclusion criteria:

1. When parent or child no longer wish to participate;

2. When a life-threatening situation occurs during the procedure (f.i. asystole);

3. When re-intervention is required as a result from subsequent bleeding;

4. When the child has to be admitted because of constant nausea/vomiting.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	19-04-0213
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-04-2013
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	NL3761

Register	ID
NTR-old	NTR3955
Other	B009201317117 : OG 009;031 E.C. Approval nr. 4157
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A