De ontwikkeling van sensorische prikkelverwerking bij peuters na het hebben ondergaan van narcose bij een electieve chirurgische ingreep in dagbehandeling.

No registrations found.

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

Summary

ID

NL-OMON24156

Source
Nationaal Trial Register

Brief title
I/T-SP ANES

Health condition

I.Primary research question:
a.) What is the influence of anaesthesia during a surgical day care procedure in a young child concerning: 1. postoperative development of sensory stimulus processing (measured with the Infant/Toddler Sensory Profile (I/T SP)); 2. changes in behaviour (measured with the Child Behaviour Checklist for ages 11/2-5 (CBCL 11/2-5)) , as determined at day 1 before intervention, up to 6 months later?
II.
Secundary research questions:
b.) What is the relation between anxiety in the child – reported preoperatively by the parent, anaesthetist and nurse by means of a Visual Analogue Scale (VAS) – and emergence delirium (ED) and the postoperative changes in the I/T SP and the CBCL 11/2 -5?c.)
What is the influence of reported pain on the postoperative changes in the I/T SP and CBCL 11/2 -5?
d.) What is the relation between the preoperative state and trait anxiety and the depression

of the parent and the child’s anxiety, evaluated by parents at induction?
e.) What is the Intraclass Correlation Coefficient (ICC) of the evaluation of anxiety by means of a Visual Analogue Scale (VAS) of the child at induction by the parents, anaesthetist and research nurse?
Keywords: anesthesia, infants, toddlers, sensory profile

Sponsors and support

Primary sponsor: Department of Anaesthesia
ZNA Middelheim -Koningin Paola Kinderziekenhuis
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2020 Antwerpen/Belgie
secretary: 032803981
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

The principal outcome measures are:

The changes measured with the I/TSP – NL 7-36 months and the CBCL 11/2- 5 in the intervention group compared to the control group.

Secondary outcome

The secundairy outcome measures:

1. The VAS scores of the child’s anxiety at induction perceived by parent as well as the research nurse and anaesthetist;

2. The ED scores by means of the Watcha scale;

3. The pain scores of the nurses by means of the FLACCnurse scale and the pain scores of the parents by means of a VASpain perception parents and VASnurse scale.

Study description

Background summary

Rationale of research:

I. Experimental study of anaesthesia on animals has shown evidence of adverse effects on the brain. An increase may be noted in programmed cell extinction (apoptosis) as well as changes in the synaptogenesis during an early (foetal/neonatal) vulnerable period in the development of the brain. Laboratory animals are thus prone to negative effects when acquiring future behaviour and when adapting their behaviour.

II. The critical period in the development of the human brain, in which damage appears after administration of anaesthesia, has not yet been determined.

Clinical experience shows that behavioural changes frequently occur after children have undergone anaesthesia. Until now these behavioural changes have been measured or evaluated with the Post-Hospital Behaviour Questionnaire (PHBQ). However, both the validity and reliability of this instrument are subject of debate. So there is definitely a need for new research in this field, with well-validated international psychological research instruments.

Aim of research:

I. Primary research question: What is the influence of anaesthesia during a surgical day care procedure in a young child concerning: 1. postoperative development of sensory stimulus processing (measured with the Infant/Toddler Sensory Profile (I/T SP)); 2. changes in behaviour and emotions (measured with the Child Behaviour Checklist for ages 11/2-5 (CBCL 11/2-5)) , as determined at day 1 before intervention, up to 6 months later?

II. Secundary research question:

A. What is the relation between anxiety in the child – reported preoperatively by the parent, anaesthetist and nurse by means of a Visual Analogue Scale (VAS) – and emergence delirium (ED) and the postoperative changes in the I/T SP and the CBCL 11/2 -5?

B. What is the influence of reported pain as measured at the day of surgery after the intervention, at day 1 postoperative and 2 weeks after the surgery on the postoperative changes in the I/T SP and CBCL 11/2 -5?

C. What is the relation between the preoperative state and trait anxiety and the depression of the parent and the child’s anxiety, evaluated by parents at induction?

D. What is the Intraclass Correlation Coefficient (ICC) of the evaluation of anxiety by means of a Visual Analogue Scale (VAS) of the child at induction by the parents, anaesthetist and research nurse?

E. What is the correlation between the estimation of pain measured with the Face, Legs, Activity, Cry, Consolability Scale (FLACC) by an independent nurse (FLACC nurse 1) and the Visual Analogue Scale (VAS pain perception parent) and the Visual Analogue Scale (VAS pain perception nurse 2) as evaluated by accompanying parent and nurse 2?

Study method:

A longitudinal case-control research in two groups of children between 18 to 30 months old. This research encloses 1. an intervention group of 100 children who undergo an elective surgical intervention under anaesthesia at the day care of the ZNA Queen Paola Children's Hospital; 2. a control group of 100 children, matched in age and socio-economic status (SES) from the population of the Antwerp 'Child and Family' [Kind en Gezin].
The longitudinal measurements are executed: 1 day before the operation, 2 weeks after, 3 months after and 6 months after the intervention. Measurements are done in the control group at similar moments and time intervals.
Use of validated measuring instruments for the Dutch language area such as the Infant/Toddler Sensory Profile-NL 7 – 36 months (I/TSP-NL 7-36), the Child behaviour Checklist for ages 11/2-5 (CBCL 11/2-5), Spielbergers State Inventory (STAI) and the Depression-anxiety-stress-scales (DASS).

Main parameters:

The principal outcome measures are:

1. The changes measured with the I/TSP – NL 7-36 months and the CBCL 11/2- 5 in the intervention group compared to the control group.

The secundairy outcome measures:

1. The VAS scores of the child's anxiety at induction perceived by parent as well as the research nurse and anaesthetist;

2. The ED scores by means of the Watcha scale;

3. The pain scores of the nurses by means of the FLACCnurse scale and the pain scores of the parents by means of a VASpain perception parents and VASnurse scale.

Study objective

Hypotheses:

1. That there will be a change in the negative sense in sensory stimulus processing after 2 weeks and possibly up to 3 months after anaesthesia as measured with I/T SP;

2. That there is a relation between postoperative changes as measured by means of I/T SP and the CBCL 11/2-5.

Hypothesis: It is assumed that there is a relation between preoperative anxiety of the child, ED and postoperative changes in the I/T SP and the CBCL 1 ½-5.

Hypothesis: Children scoring high on pain in the postoperative phase will probably show more signs in negative sense such as measured by the I/T SP and the CBCL 1½-5.

Hypothesis (d-e): It is assumed that anxious and rather depressive parents will evaluate the anxiety of their child differently.

Study design

Measurements are done at four moments: 1 day before the operation, 2 weeks after the intervention and postoperatively after 3 months and 6 months. In the control group 3 measurements are done at similar moments (the follow-up measurement of 2 weeks is cancelled).

Intervention

This study is a longitudinal case-control research in 200 children aged between 18 and 30 months, divided in:

1. An intervention group (n = 100);

2. A control group (n = 100).

The intervention group undergoes an intervention under anaesthesia in the day care hospital of the Queen Paola Children's Hospital. The control group of 100 children, matched in age and socio-economic status, are studied via the Antwerp 'Child and Family' [Kind en Gezin] (Provincial department Antwerp, Lange Kievitstraat 111 bus 32, Antwerp, tel: 03-224 61 01).

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Eligibility criteria

Inclusion criteria

1. Age from 18 up to and including 30 months and of male sex (intervention and control group);

2. Healthy children without a medical record or congenital disorders (intervention and control group);

3. Children who undergo a circumcision under anaesthesia because of religious reasons in the day care hospital;

4. Written permission (Informed consent);

5. Parents who speak and understand Dutch;

6. Accompanying parent during induction anaesthesia.

Exclusion criteria

1. No previous medical/surgical interventions under anaesthesia in the child (both intervention and control group);

2. Children who need a circumcision because of medical reasons;

3. No previous hospital admissions of the child (both intervention and control group);

4. All kinds of known limitations among which an intellectual limitation, speech or language defect, autism/pervasive development disorder (PDD), delayed development, ...
they are all mentioned on the score form of the I/TSP-NI 7 up to and including 36 months;

5. Parents and children who do not speak and understand Dutch;

6. Parents who do not give permission for the research.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2012
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-02-2012
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	NL3162

Register	ID
NTR-old	NTR3306
Other	METC ZNA : 3952
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A