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Evalution of influence of audiovisual information on anxiety of parents present at induction of anaesthesia

Submission date	Recruitment status	[ ] Prospectively registered
02/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/05/2010	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AR001

Study information

Scientific Title
Evaluation of the influence of audiovisual information on the anxiety and contentement of the parent present during the induction of anaesthesia on children

Acronym
Anredaud

Study objectives
Offering audiovisual information may influence pre-operative and post-operative state anxiety of the parents of a child undergoing surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee (MREC) - Ziekenhuisnetwerk Antwerpen (ZNA) approved on the 10th February 2010 (ref: 3541)

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anxiety reduction

Interventions
This is randomised double-blind research in which 120 parents will take part who will accompany the child to the operating room. After filling out the admission form, we collect the following demographic data of the parents and the child: the age, gender of the parent present, the parent's native language, type of surgery, whether or not it is the first surgery the child undergoes, if the parents have other children who have undergone surgery, the highest qualification of the parents and if there has been a prior consultation between the parents and the anaesthetist (this will take 5 minutes).

All parents receive standard written information about what the anaesthesia implies and what will precisely happen at the induction. No premedication is given. During the whole course, a voluntary worker will be present.

At admission (the day of the surgery), the parents and their child are randomised in a control group and an intervention group. We are going to use blind-numbered envelopes to do this. This randomisation will be carried out using computer generated numbers. Men as well as women will be included in this.

After that, we will verify the anxiety score of the parent present. We will use the State-Trait Anxiety Inventory (STAI) and the Amsterdam Preoperative Anxiety and Information Scale (APAIS), the latter also questions the need for information. Every parent present will also be asked to fill in the two questionnaires. This will take approximately 10 minutes.

The intervention group will then receive audiovisual information, in the form of a short movie (duration: 4 minutes), the control group does not see the movie. This movie will describe the hospitalisation, the transport to the operating room, the induction and the induction of the anaesthesia by telling a story about the journey of young boy to "Groenland" (Greenland), a metaphor for our operating room, together with his friend "Mister Dragon". During the journey, the young boy meets Caroline and together with his mum he arrives in Groenland. The movie was shot at the Koningin Paola Kinderziekenhuis.

After this, we will ask the both parental groups to fill in the state-part of the STAI (Spielberger) and the APAIS again (this will take approximately 4 minutes). After this, the child and the parent present will be guided to the operating room.

During the induction, the anaesthetist fills in the Induction Compliance Checklist (ICC) and the Visual Analogue Scale (VAS). The anaesthetist does not know to which group the parent has been allocated.

The ICC is developed to score the childs behaviour during the induction of anaesthesia. The list consists of 11 items indicating the level obligingness of the child at induction. The total score = the amount of categories checked (perfect score = 0).

The VAS is a 100 mm horizontal line with two behavioural extremes (not anxious to very anxious) on both ends. The anaesthetist marks how anxious the child is during induction.

After the induction of the anaesthesia on the child, the parent and the voluntary worker leave the operating room. All parents are asked to fill in the state anxiety part of the STAI (Spielberger) and the APAIS again (duration: 4 minutes).

All accompanying parents will also be asked to fill in a short additional questionnaire which will assess the general satisfaction level, the quality of the provided preoperative information and the benefit of the provided audiovisual information (intervention group only). We use a VAS scale for which the parent is asked to put a mark between the two extremes.

The questions are:
1. Were you satisfied about the given information in connection to the anaesthesia? (absolutely not to very satisfied)
2. Were you very motivated to be present at the induction of anaesthesia? (not to absolutely want to be present)

3. Do you believe that your presence is useful for your child? (not useful to absolutely necessary)
4. Are you satisfied with the course of the procedure? (totally not to very satisfied)
5. Do you think that giving audiovisual information is useful for the preparation of anaesthesia? (intervention group only) (totally not to very useful)

The anxiety which the child has experienced according to the parent during the induction is also measured by means of a VAS scale. As previously discussed, the VAS scale is a 100 mm horizontal line with two behavioural extremes (not anxious to very anxious) which are on either side of the scale. The parent present marks the level of anxiety during induction of the child.

6. How anxious was your child according during the induction? (totally not anxious to very anxious)

This will take an additional 5 minutes. The total duration to fill in the questionnaires in both arms (intervention and control) will be 28 minutes. The intervention group will see the audiovisual information (short movie) which will take another 4 minutes, therefore the total duration of treatment in the control group will be 28 minutes and the total duration of treatment in the intervention group will be 32 minutes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
State anxiety reduction reduction (STAI Spielberger and APAIS), measured at admission (T1), after viewing (or not) the audiovisual information (T2) just before entering the operating theatre and when the parents leave the operating theatre (T3).

Secondary outcome measures
1. Correlation between state anxiety and trait anxiety (STAI Spielberger), measured at admission (T1), after viewing (or not) the audiovisual information (T2) just before entering the operating theatre and when the parents leave the operating theatre (T3)
2. Correlation between need for information (information part of the APAIS) and the state/trait anxiety (state part of APAIS and STAI Spielberger), measured at admission (T1)
3. Correlation between Induction Compliance Checklist (ICC) and anxiety measure of the child at induction by using a VAS. Both measurements are done after induction by the anaesthetist (Tafter induction anaesthetist).
4. Anxiety measure of the child (by the parent) at induction by using a VAS. This will be done after induction by the parent, when the parent has left the operating theatre (Tafter induction parent). Correlation will be sought between VAS (Tafter induction parent) and the ICC (Tafter induction Anaesthetist).
5. Satisfaction measurement of the parents by using a VAS (Tafter induction parent)

Overall study start date
15/02/2010

Completion date
01/08/2010

Eligibility

Key inclusion criteria
1. Children aged older than 6 months, either sex
2. Written consent ('Informed Consent')
3. Parents who understand and speak Dutch
4. Parent present at induction
5. No premedication
6. Parent of a child undergoing surgery in a daycentre
7. American Society of Anaesthesiologists classification (ASA) 1 - 2 and 3

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Not understanding/speaking Dutch
2. No consent for the research
3. Children younger than 6 months

Date of first enrolment
15/02/2010

Date of final enrolment
01/08/2010

Locations

Countries of recruitment
Belgium

Study participating centre
Lindendreef 1
Antwerp
Belgium
2020

Sponsor information

Organisation
ZNA Middelheim - Queen Paola Childrens Hospital (Belgium)

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Sponsor type
Hospital/treatment centre

Website
http://www.zna.be

ROR
https://ror.org/01z5jvj74

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
ZNA Middelheim - Queen Paola Childrens Hospital (Belgium) - Department of Anaesthesia and Reanimation

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration