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Parental misconceptions about pain medication and their child's pain at home

Submission date 07/06/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/06/2023	**Overall study status** Ongoing	
Last Edited 13/06/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The majority of surgeries on children are done in the day hospital. Parents play a major role at home in their child's postoperative care and an important issue therefore is the timely recognition and adequate treatment of pain, which is not always easy. This study aims to assess the knowledge of pain medication and certain predictive factors. Furthermore, parents' thoughts and feelings about their child's perception of pain are examined. This may result in better pain management in children in the day hospital.

Who can participate?
Parents of children aged between 3 months and 15 years who will soon undergo surgery under anaesthesia at the Koningin Paola Children's Hospital or Jan Palfijn Hospital can participate.

What does the study involve?
Parents will have spoken to the doctor about their child's operation and the aftercare. To participate in this study, the child must be undergoing surgery in the day hospital. On the day of surgery, a member of the research team will have a discussion with them about the proposed study. They will explain the study again and answer any questions. If they wish to participate in this study, they can sign the consent form, after which the researcher will also sign it.

Parents will then complete some questionnaires before the procedure concerning:
1. The anaesthesia and procedure
2. Their knowledge and attitude towards giving pain medication to their child
3. Their thoughts and feelings when their child is in pain
Completing these questionnaires will take about 10 to 15 minutes. They can then accompany their child into the operating room.

Once at home after the procedure, the research team will ask parents to keep a diary for three days in which they score behavioural changes in their child twice a day (in the morning after breakfast and in the evening after dinner) by filling in the above-mentioned questionnaire as well as a scale on which they can indicate the pain they think their child is experiencing at that moment. Furthermore, they also ask them to note the pain medication their child has taken. They will provide a general brochure on pain management in children on the day of surgery.

When the child is discharged, parents will be given sufficient additional information so that they can give the necessary care at home. They will receive a sufficient explanation of how to fill in these diaries. They will be contacted twice by telephone by one of our staff members to check that there are no problems. Afterwards, they will be asked to return the diaries in a stamped envelope to the anaesthesia office of ZNA Middelheim - Koningin Paola Children's Hospital.

It is also very important that participants cooperate and follow the instructions given to them by the study personnel.

What are the possible benefits and risks of participating?
As mentioned above, the treatment offered for the child and the procedures for diagnosis and follow-up correspond to good medical practice. There is no change to the care the child receives both before, during and after the procedure. The child will receive the same treatment as children not taking part in the study. There are no additional risks associated with the study. The child will have no direct benefit from participating in this study, other than possibly the extra personal attention they will receive.

The postoperative pain medication prescribed is the same as that prescribed to children not participating in this study. Importantly, when taking non-steroidal anti-inflammatory drugs (e.g. Nurofen, Ibuprofen), sufficient water should be drunk to reduce the risk of kidney problems.

Withdrawal of consent
Participation in this study is completely voluntary and should never be done under pressure. Participants have the right not to participate in the study. They may also withdraw from the study at any time without having to give any reason, even if they had previously consented. If they withdraw consent, the data collected up to the time of withdrawal will be retained to ensure the validity of the study. No further new data will be transferred to the commissioner. The study's physician-researchers could also decide to discontinue the study if the data collected provide a response sooner than anticipated.

The clinical trial sponsor, ZiekenhuisNetwerk Antwerpen (ZNA) or Hospital Network Antwerp, has taken out insurance for this study. There will be no additional charge on top of the standard cost for this surgical procedure. The clinical trial sponsor and all persons involved are bound by professional confidentiality. The personal data of participants will be treated completely anonymously and the study has been evaluated by the various research members and independent members and it has been approved by the ZNA Ethics Committee. Participants may not participate in another clinical trial simultaneously without notifying the researcher or study personnel.

Where is the study run for?
ZiekenhuisNetwerk Antwerpen (ZNA) (Belgium)

When is the study starting and how long is it expected to run for?
September 2022 to October 2025

Who is funding the study?
The Department of Anesthesiology ZiekenhuisNetwerk Antwerpen (ZNA) (Belgium)

Who is the main contact?
Johan Berghmans MD PhD, johan.berghmans@zna.be

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
B0092023000085

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MAQADhpred

Study information

Scientific Title
Parental misconceptions about pain medication, parental pain medication adherence and their child’s pain at home after daycare surgery - A prospective observational cohort study

Acronym
PSNSB-ANB-RCT

Study objectives
It has been observed that up to 80% of children undergoing daycare surgery suffer a lot of pain at home. This might be the result of poor pain management but nevertheless, the issue is complex given the specific child, organizational system, medication and parental factors which should be taken into account. Parental-related psychological determinants are considered to be very important.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/02/2023, ZNA Medical Ethics Committee Institutional Review Board (ZNA/OCMW Antwerpen, Lindendreef 1, Antwerpen, 2020 , Germany; +32/32803429; ethische-commissie@zna.be), ref: 5785

Study design
Cross-sectional cohort study with three days longitudinal follow-up

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home, Hospital, Telephone

Study type(s)

Diagnostic, Prevention

Participant information sheet
Not availible in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Study of parental misconceptions about pain medication and their child’s pain at home

Interventions
This is a prospective analytic observational longitudinal cohort study up to three days postoperatively. Firstly, this study aims to assess parental misconceptions about the child’s pain medication. Secondly, to investigate possible associations between these misconceptions about pain medication and parental gender, education level, cultural/religious aspects, health beliefs mindset, level of expected pain, type of surgery, parental state anxiety/distress, need for information, parental sympathizing and pain catastrophizing thoughts (state/trait). Thirdly, this study assesses the level of postoperative pain and pain medication adherence at home in children aged 3 months - 15 years during the first three days after daycare surgery and investigates the possible associations between postoperative pain/pain medication adherence on the one hand and on the other the existing parental misconceptions, gender, education level, cultural/religious aspects, health beliefs mindset, level of expected pain, type of surgery, state anxiety/distress, need for information, sympathizing and pain catastrophizing thoughts (state /trait).

The interventions are well-validated questionnaires, filled in by the parents, prior to the surgical intervention with the assistance of a research nurse. After the procedure, parents are asked to assess their child’s pain using a well-validated questionnaire and medication adherence during three postoperative days. Postoperative telephone calls (day 1 and day 3 postoperative) are made by research nurses.

Intervention Type
Other

Primary outcome measure
1. Parental misconception about their child's pain medication measured using the Medication Attitude Questionnaire (MAQ) at baseline.
2. Pain at home measured by the parents using the Parents’ Postoperative Pain Measure (PPPM) and a Numerical Rating scale – Pain (NRS-P), both scales twice a day during the three consecutive postoperative days
3. Parental adherence to the pain management of their child at home measured using the total number of pain medications given to their child, once a day during three postoperative days

Secondary outcome measures
1. State Anxiety measured using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) at baseline (once)
2. Parental distress and sympathy measured using Numerical Rating Scales (NRS-distress and NRS-sympathy) at baseline
3. The expected postoperative pain measured using the Expected Numerical Rating Scale postoperative pain (NRS-P-expected) at baseline
4. Health beliefs measured using the Parental Health Beliefs scale (HBS) at baseline
5. Trait pain Catastrophizing measured using the Trait Pain Catastrophizing Scale for parents –

Trait (PCS-P-Trait) at baseline
6. State pain catastrophizing measured using the State Pain Catastrophizing Scale for parents – State (PCS-P-State) at baseline

Overall study start date
01/09/2022

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Parents who accompany their child aged between 3 months and 15 years old for a surgical intervention under anesthesia in daycare
2. The children undergo different kinds of surgery (general, orthopedic, urologic, maxillofacial and ear nose throat surgery)
3. Children with American Society of Anesthesiologists physical status (ASA I-II)
4. Parents with a good understanding of the Dutch language
5. Written informed consent

Participant type(s)
Population, Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
285

Total final enrolment
285

Key exclusion criteria
1. Parents of a child with a known mental/cognitive retardation
2. Parents of children with an American Society Anesthesiologists ASA physical status > II
3. When the parent no longer wishes to participate
4. When a life-threatening situation occurs during the procedure (f.i. asystole)
5. When re-intervention is required as a result of subsequent bleeding after a tonsillectomy
6. When the child has to be admitted because of constant nausea/vomiting

Date of first enrolment
22/06/2023

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
Belgium

Study participating centre
ZiekenhuisNetwerk Antwerpen (ZNA)
Lindendreef 1
Antwerp
Belgium
2020

Sponsor information

Organisation
Ziekenhuisnetwerk Antwerpen Stuivenberg

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Department of anesthesiology
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Sponsor type
Hospital/treatment centre

Website
http://www.zna.be

ROR
https://ror.org/05dpzfc16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ziekenhuis Netwerk Antwerpen (ZNA)

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Johan Berghmans MD PhD, johan.berghmans@zna.be

The type of data that will be shared is anonymized raw data, which will be available at the end of the study. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0		13/06/2023	No	No
Statistical Analysis Plan	version 1		13/06/2023	No	No