

Testing the Dutch version of the Parents' Postoperative Pain Measure (PPPM)

Submission date 21/10/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims.

More and more operations in children take place in an outpatient setting (no overnight stay in hospital). Consequently, parents at home play an increasingly important role in the postoperative care of their child.

An essential part of this care is to recognize and treat pain, which is not always evident in children because they also show certain behavioral changes after an operation. Queen Paola Children's Hospital is currently conducting research into these behavioral changes in children after an operation and pain measurements by parents.

Who can participate?

Children between 2 and 12 years old who will undergo an outpatient operation.

What does the study involve?

Prior to the operation parents fill in a questionnaire concerning their child's behavior.

Once back home after the operation the parent will keep a diary for five days, in which the behavioral changes of the child are scored twice a day (in the morning after breakfast and in the evening after supper).

If the child is older than 6, they will be provided with a diary to indicate a pain score by means of a face scale twice a day done at the same time as the parent diary.

What are the possible benefits and risks of participating?

None

Where is the study run from?

ZNA Middelheim - Queen Paola Children's hospital (Belgium)

When is the study starting and how long is it expected to run for?

December 2019 to February 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Johan Berghmans, johan.berghmans@zna.be

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

E.C. 5394

Study information

Scientific Title

The Dutch version of the Parents' Postoperative Pain Measure (PPPM) – validity and reliability in the assessment of postoperative pain among children aged between 2 and 12 years

Acronym

PPPM-D-form

Study objectives

To establish the reliability, validity, and sensitivity to change overtime (longitudinal sensitivity) of the Dutch version of the Parents' Postoperative Pain Measure (PPPM-D) in the assessment of postoperative pain among children aged between 2 and 12 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/07/2020, Commissie voor Medische Ethiek ZNA, Institutional Review Board (ZNA /OCMW Antwerpen, Lindendreef 1, 2020 Antwerpen, Belgium; +32(0)32803429;), ref: 009;OG 031; E.C. 5394

Study design

Single-centre prospective observational study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Assessment of postoperative pain

Interventions

A formal forward-back-forward translation procedure to translate the PPPM into Dutch (PPPM-D) will be carried out. Furthermore an expert panel of two psychologists and two anesthesiologists will evaluate the translation.

This prospective observational study aims to include 120 children stratified according to:

1. Child's age - age between 2-5 and between 6- 12 years of age (dichotomy based on the child's ability to self-report of pain intensity by using the Faces Pain Scale Revised – FPS-R)
2. Different kinds of surgery (general, orthopedic, urologic, maxillofacial and otolaryngologic) related to the expected level of postoperative pain intensity levels (mild, moderate, severe).

After receiving precise instructions one accompanying parent will complete the PPPM-D at the day of surgery (before the intervention) and directly after surgery in the evening and this parent will later rate the child's pain twice a day (morning-evening) during the first 5 postoperative days. In parallel with the PPPM assessments, parents will also use a Numerical Rating Scale (NRS) to assess the pain of their child. Also, children between 6 and 12 years will rate their pain intensity twice a day during 5 days postoperative by using the Faces Pain Scale Revised (FPS-R).

Intervention Type

Other

Primary outcome(s)

Pain measured using the Dutch version of Parents' Postoperative Pain Measure (PPPM-D) two times each day by parents (after breakfast and in the evening after dinner) during five consecutive days. Parents will also fill in the PPPM-D on the day of surgery before the intervention as basic assessment

Key secondary outcome(s)

1. Pain measured using a Numerical Rating Scale (NRS-11) two times each day by parents (after breakfast and in the evening after dinner) during five consecutive days. Parents will also fill in the NRS on the day of surgery before the intervention as basic assessment
2. Pain measured using the Faces Pain Scale-Revised (FPS-R) two times each day during 5 postoperative days (self report by the children)

Completion date

28/02/2023

Eligibility

Key inclusion criteria

1. Children 2 – 12 years old
2. Information and consent forms for parents and an assent form explained to the child
3. Undergoing one of the following surgical procedures: inguinal hernia repair, myringotomy, adenoidectomy, gastroscopy, dental surgery, orchidopexy, strabismus, circumcision, adenotonsillectomy, orthopedic osteosyntheses
4. One accompanying parent present at induction
5. Parents who speak and understand Dutch
6. No premedication

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

12 years

Sex

All

Total final enrolment

120

Key exclusion criteria

1. Known mental/cognitive retardation
2. American Society Anesthesiologists ASA physical status >II

Date of first enrolment

01/11/2020

Date of final enrolment

31/08/2022

Locations

Countries of recruitment

Belgium

Study participating centre
ZNA Middelheim - Queen Paola Children's Hospital
Lindendreef 1
Antwerpen
Belgium
2020

Sponsor information

Organisation
ZNA Middelheim Hospital

ROR
<https://ror.org/01z5jv74>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			22/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1.0	26/05/2020	06/11/2020	No	No