

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

<b>Submission date</b> 21/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/01/2024	<b>Condition category</b> 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?
<a href="#">Results article</a>			22/01/2024	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version v1.0	26/05/2020	06/11/2020	No	No