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

Submission date 21/10/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/10/2020	**Overall study status** Completed	
Last Edited 22/01/2024	**Condition category** Other	

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
Dr Johan Berghmans

ORCID ID
http://orcid.org/0000-0002-3835-562X

Contact details
Wijerveldstraat 69
Hasselt
Belgium
3500
+32 (0)478496755
johan.berghmans@zna.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

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

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 measure
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

Secondary outcome measures
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)

Overall study start date
01/12/2019

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

Age group
Child

Lower age limit
2 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
120

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

Sponsor details
Lindendreef 1
Antwerpen
Belgium
2020
+32 (0)32803993
stefaan.goossens@zna.be

Sponsor type
Hospital/treatment centre

Website
http://zna.be

ROR
https://ror.org/01z5jvj74

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
28/07/2023

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?
Protocol file	version v1.0	26/05/2020	06/11/2020	No	No
Results article			22/01/2024	Yes	No