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Psychological predictors explaining postoperative pain after third molar surgery

Submission date	**Recruitment status**	[X] Prospectively registered
03/03/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/03/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2023	Surgery	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether patients still feel a lot of pain at home after wisdom tooth extraction (postoperative pain) and whether differences in reported pain scores between patients are due to personal characteristics already present before the surgery. This study is unique because studies have so far mainly examined pain experience after wisdom tooth extraction under local anesthetic while this study focuses on the pain experienced after wisdom tooth extraction under general anesthetic.

Who can participate?
Patients aged 18 – 40 years undergoing extraction of one or more third molars (back teeth) under general anaesthesia in the ZNA Middelheim/Jan Palfijn hospital

What does the study involve?
The first survey, which will be conducted before surgery, will look at those personal characteristics that have influenced postoperative pain experiences in other studies. These characteristics are age, gender, weight and height, level of education, need for information, presence of anxious or depressed feelings and the way one deals with pain. This initial questionnaire takes about 7 minutes to complete. After the operation, participants will be requested to note both their pain score and their medication twice a day for a further 7 days. This will only take 1 to 2 minutes each time. The researchers also want to enquire about participants' functional recovery on a daily basis. This questionnaire is a little longer and takes a maximum of 5 minutes to complete.

What are the possible benefits and risks of participating?
If the researchers have sufficient results, they can anonymously analyze all the data collected and stored in a privacy-safe manner. From these results, they can subsequently draw some conclusions, which they hope to publish in a medical journal. If they can conclude from this research that the experience of pain at home after this operation is indeed still a problem, or if they find a relationship between personal characteristics, this may improve the pain experience for other patients in the future. As mentioned above, the proposed treatment and the procedures for diagnosis and follow-up correspond to good medical practice. There will be no change in the care participants receive before, during and after the procedure. They will receive

the same treatment as patients who do not participate in the study. No additional risks are associated with the study.

Where is the study run from?
ZiekenhuisNetwerkAntwerpen (ZNA) Middelheim and ZNA Jan Palfijn (Belgium)

When is the study starting and how long is it expected to run for?
September 2021 to January 2023

Who is funding the study?
Ziekenhuisnetwerk Antwerpen (ZNA) (Belgium)

Who is the main contact?
Dr J. Berghmans
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
B0092022000058

Study information

Scientific Title
The influence of pain catastrophizing, state anxiety, need for information and depression on postoperative pain intensity and functional recovery at home after surgical third molar removal under anesthesia: a prospective observational cohort study

Acronym
PPePPversion-1

Study objectives
The hypothesis: a majority of the patients will suffer from moderate to severe pain and will experience a significant impact on functional recovery up to 7 days after surgery. Furthermore, pain catastrophizing, state anxiety, need for information and depressive thoughts will be associated with postoperative pain intensity at home and with functional recovery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/02/2022, Institutional Review Board - ZNA/OCMW Antwerpen (Lindendreef 1, 2020 Antwerpen Belgium; +32 (0)32803429; ethische-commissie@zna.be), ref: 009; OG 031

Study design
Prospective observational longitudinal 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
Postoperative pain and functional recovery after ambulatory surgery for third molar extraction

Interventions
This is a prospective observational cohort study. Postoperative pain and functional recovery will be assessed during the first 7 days and at day 14 after ambulatory surgery for third molar extraction. Furthermore, preoperative assessment of modifiable psychological factors (like pain catastrophizing, state anxiety, need for information, depressive thought) will be evaluated.

Intervention Type

Other

Primary outcome measure
1. Postoperative pain measured using the Visual Analogue Scale – Pain (VAS-P) three times during the day of surgery (immediate postoperative, during the post-anesthesia care unit (PACU) stay and at 8 PM at home) and from day 1 up to day 7 postoperatively twice a day (at 8 AM and 8 PM)
2. Functional recovery measured using the Functional Recovery Index (FRI) once a day from day 1 up to day 7 postoperatively

Secondary outcome measures
1. Pain catastrophizing measured using the Pain Catastrophizing Scale (PCS), preoperative at the day of the intervention
2. State anxiety measured using the Amsterdam Preoperative Anxiety and Information Scale (APAIS), preoperative at the day of the intervention
3. Need for information measured using the Amsterdam Preoperative Anxiety and Information Scale (APAIS), preoperative at the day of the intervention preoperatively
4. Depressive thoughts measured using the Hospital Anxiety and Depression Scale (HADS), preoperative at the day of the intervention

Overall study start date
01/09/2021

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Patients aged 18 – 40 years undergoing extraction of one or more third molars under general anaesthesia in the ZNA Middelheim/Jan Palfijn hospital
2. American Society of Anesthesiologists physical status (ASA I-II)
3. A good understanding of the Dutch language
4. Written informed consent
5. Without premedication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
145

Total final enrolment
144

Key exclusion criteria
1. Refusal to participate
2. Patients with a known development delay and intellectual disability
3. Intolerance for local anesthetics and non-steroidal anti-inflammatory drugs (NSAIDs)
4. Chronic use of opioids

Date of first enrolment
15/03/2022

Date of final enrolment
24/01/2023

Locations

Countries of recruitment
Belgium

Study participating centre
ZNA Middelheim - ZNA Jan Palfijn
ZiekenhuisNetwerkAntwerpen (ZNA) Middelheim
Lindendreef 1
Antwerpen
Belgium
2020

Study participating centre
ZNA Jan Palfijn
Lange Bremstraat 70
Merksem
Belgium
2170

Sponsor information

Organisation
Ziekenhuisnetwerk Antwerpen Stuivenberg

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

Sponsor type
Hospital/treatment centre

Website
https://www.zna.be

ROR
https://ror.org/05dpzfc16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ziekenhuisnetwerk Antwerpen (ZNA)

Results and Publications

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

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	24/01/2022	07/03/2022	No	No