ISRCTN77862744 https://doi.org/10.1186/ISRCTN77862744

The effect of pre-emptive pain relief to prevent postoperative pain in children

Submission date	Recruitment status	[_] Prospectively registered
22/04/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/04/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/06/2022	Surgery	

Plain English summary of protocol

Background and study aims
This study will investigate a method that aims to reduce the intensity of pain in children undergoing Ear, Nose, and Throat (ENT) surgical procedures of removal of the palatine tonsils (tonsillectomy) and adenoid (adenotomy) at the University Hospital in Wroclaw. Pain caused by surgery is the main reason for a child's discomfort period following the surgery. Pre-emptive pain relief is a procedure that is initiated before the onset of the pain stimulus and leads to blocking the pain signal, coming from the surgical wound.

The aim of this study is to evaluate how effective pre-emptive pain relief is in preventing postoperative pain, after ENT surgical procedures in children.

Who can participate?
Healthy children between the ages of 3 and 17 years, who are qualified for surgical treatment in an ENT clinic

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). The participants in the first group will be given a pain relief drug (paracetamol) before surgery, in addition to the standard preparation for surgery. The dose of the drug will be adjusted according to the child's weight. The participants in the second group will be given an identical looking treatment with no active medicine before surgery, in addition to the standard preparation for surgery. After surgery participant pain levels will be assessed.

What are the possible benefits and risks of participating?
Paracetamol is a drug that has long been widely used for the treatment of pain in home and hospital settings. The device used to measure pain via skin conductance is noninvasive and painless. The use of pre-emptive analgesia will allow to individually adjust pain therapy to the child's needs. The results of the study will answer the question of whether this method has an effect on the reduction of postoperative pain in children. It is hoped that effectively treated pain will contribute to an increase in comfort for the child hospitalized at the department and a reduction in the length of hospitalization.

Where is the study run from?
Wroclaw Medical University (Poland)

When is the study starting and how long is it expected to run for?
From May 2018 to March 2022

Who is funding the study?
Investigator initiated and funded study

Who is the main contact?
Dr Jakub Zielinski
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of Pre-Emptive Analgesia on the Postoperative pain IN pediatric otolaryngology: a randomized, controlled trial

Acronym
P-EAPIN

Study objectives
The administration of pre-emptive analgesia reduces the severity of postoperative pain in children

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/08/2018, Ethical Committee of the Medical University of Wrocław (Pasteura 1, 50-367 Wrocław, Poland; +48717841014; bioetyka@umed.wroc.pl), ref: KB–459/2018

Study design
Single-center interventional double-blinded randomized controlled trial.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Postoperative pain in children

Interventions
The study will randomly allocate a patient to an intervention or control group, using permuted block randomization. The intervention group will receive pre-emptive analgesic paracetamol orally (15 mg/kg) and the control group will receive a placebo in addition to midazolam (0.5 mg /kg) as premedication. All children are administered sevoflurane gas, intravenous propofol (between 2 and 4 mg/kg), and fentanyl (2 mcg/kg). During the surgery, all patients receive intravenous dexamethasone (0.2 mg/kg) and nalbuphine (0.2 mg/kg) as standard perioperative analgesia.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
paracetamol, midazolam, sevoflurane gas, propofol, fentanyl, dexamethasone, nalbuphine

Primary outcome(s)
Postoperative pain measured using the Visual Analogue Scale (VAS), the Wong–Baker Faces Pain Rating Scale, and the Face, Legs, Activity, Cry, and Consolability (FLACC) scale at 1, 2, 4, and 6 h after surgery

Key secondary outcome(s))
Current secondary outcome measures as of 21/06/2022:
There are no secondary outcome measures

Previous secondary outcome measures:
Discomfort with self-adhesive electrodes or cannulation after surgery measured by asking to locate the site of pain in postoperative assessment at 1, 2, 4, and 6 h after surgery

Completion date
01/03/2022

Eligibility

Key inclusion criteria
1. Aged between 3 and 17 years
2. Otolaryngological procedure needed
3. Written informed consent to participate in the study from parents (or legal guardians)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
17 years

Sex
All

Total final enrolment
51

Key exclusion criteria
1. Intellectual disability
2. Major coexisting diseases
3. Allergy to paracetamol, dexamethasone, or nalbuphine
4. Pain prior to surgery

Date of first enrolment
19/07/2019

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
Poland

Study participating centre
University Hospital in Wroclaw
Department of Otolaryngology
Head and Neck Surgery
Borowska 213
Wrocław
Poland
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Sponsor information

Organisation
Wroclaw Medical University

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Jakub Zieliński (zielinski.kuba@gmail.com). Anonymized data available will be available from January 2022, with no time restrictions, and will be shared with healthcare professionals, for research only. Consent from participants was obtained with no ethical or legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/05/2022	21/06/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes