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Local anaesthesia for prevention of pain after removal of tonsils in adult patients

Submission date
11/11/2011

Recruitment status
No longer recruiting

Registration date
09/12/2011

Overall study status
Completed

Last Edited
06/11/2012

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Treatment of postoperative pain after tonsillectomy is challenging. During first postoperative week pain is intense. Commonly used ibuprofen and paracetamol-codein combination or tramadol hydrochloride are not sufficient for adequate pain treatment at home. New methods are needed. Topical anaesthesia with ropivacaine is a safe, simple and easy method to prevent pain but we do not know well enough whether this method works.
The aim of this study is to test how well topical ropivacaine works on prevention of postoperative pain in adult patients for two postoperative weeks.

Who can participate?
160 adult patients scheduled for elective day-surgery tonsillectomy will be recruited.
We will be recruiting patients for approximately 6-8months to reach the goal of 160 patients.
We will try to recruit 8 patients per week.

What does the study involve?
After tonsillectomy has been performed under general anaesthesia, each tonsillar fossae will be tightly packed with two swabs containing either 80mg ropivacaine or saline. After five minutes, swabs will be removed and after that general anaesthesia terminated and patient extubated. Other than that, patients will receive standard care. Pain will be evaluated in the post-anesthesia care unit (PACU) for two hours. After discharge, patients will receive daily for two weeks an email containing a link to a questionnaire in a database. Patients will be asked to answer questions on pain and other symptoms, as well as the amount of pain medication used.

What are the possible benefits and risks of participating?
There is no additional risk to patients compared to the normal clinical procedure, in which local infiltration anaesthesia is sometimes used to prevent postoperative pain. When local anaesthesia is used after tonsillectomy, there is a possibility that patients might have trouble in swallowing, so this will be monitored closely after the operation.

Where is the study run from?
The study will be run in the Helsinki University Central Hospital, Eye-Ear Clinic, by the Department of Otorhinolaryngology and the Department of Anesthesia and Intensive Care Medicine. There is only one trial centre.

When is the study starting and how long is it expected to run for?
The study will start in January 2012 and is expected to run until December 2012.

Who is funding the study?
The study is funded by the Helsinki University Central Hospital Research Funds, Helsinki, Finland.

Who is the main contact?
Dr Vesa Kontinen
vesa.kontinen@hus.fi

Contact information

Type(s)
Scientific

Contact name
Dr Vesa Kontinen

Contact details
Haartmaninkatu 2
Helsinki
Finland
00029
+358 09 4711
vesa.kontinen@hus.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HYKSKIPU2011-1

Study information

Scientific Title
Topical anaesthesia for postoperative pain in adult patients undergoing tonsillectomy

Study objectives
Topical anaesthesia will improve pain relief after tonsillectomy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, Department of Surgery, Helsinki University Central Hospital approved the study on 14th of September 2011

Study design
Single-centre double-blinded randomized controlled prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Tonsillectomy

Interventions
After the operation, each tonsillar fossae will be tightly packed with two swabs containing either 80mg ropivacaine (study group) or same amount of saline (placebo). After five minutes, swabs will be removed. Otherwise tonsillectomy will be carried out as usual.

To make sure that every swab contains equal amount of ropivacaine or saline, swabs will be dipped in 20ml of eather ropivacaine or saline, and extra liquid pressed out. After that they will be tightly packed in tonsillar fossae.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ropivacaine

Primary outcome measure
Pain intensity when swallowing measured on NRS 0-10 (0 no pain, 10 worst possible pain) during 7 postoperative days. Area under curve (AUC) of the pain intensity will be calculated.

Secondary outcome measures
1. Worst pain during two hours followup in post-anesthesia care unit (PACU)
2. The amount of pain and pain medication during 14 postoperative days

Overall study start date
01/01/2012

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Adult patients age over 18 years scheduled for elective day-surgery tonsillectomy, operation under general anaesthesia
2. American Society of Anaesthesiologists (ASA) class I and II

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160 patients: 80 in study group and 80 in control group.

Key exclusion criteria
1. Peritonsillary abscess 2 weeks preoperatively
2. Suspicion of malignancy
3. Haemostatic disorder
4. Regular analgesic use
5. Antidepressant medication
6. Allergy or contraindication to research medication
7. Weight less than 50kg or more than 120kg
8. Inability to communicate in Finnish or Swedish
9. Inability to use Numerical rating scale (NRS) pain scale

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
Finland

Study participating centre
Haartmaninkatu 2
Helsinki
Finland
00029

Sponsor information

Organisation
Helsinki University Central Hospital (Finland)

Sponsor details
Haartmaninkatu 2
Helsinki
Finland
00029
+358 04711 2010
vesa.kontinen@hus.fi

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Central Hospital (Finland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration