Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Comparison the effect of oral oxycodone Vs oral meloxicam on pre-emptive control of postoperative pain after tonsillectomy in adults

Protocol summary

Study aim
Comparison of the effect of oral oxycodone with oral meloxicam on preventive pain control after tonsillectomy surgery in adults.

Design
Clinical trial with parallel groups, triple blind, randomized, phase 2-3 on 70 patients. Random Elocit software will be used for randomization

Settings and conduct
This study is a randomized, controlled, triple-blind clinical trial, which aims to compare the effect of preventive prescription of two drugs, oxycodone and oral meloxicam, on pain control after tonsillectomy surgery in adults referred to Bou Ali Sina Sari Medical Training Center. 70 candidates for tonsillectomy, including adults with anesthesia class 1 and 2 (ASA), are selected as available. Sampling of all patients over 18 years of age who referred to Bo Ali Sina Hospital in Sari during the fall and winter of 1402, who are candidates for planned tonsillectomy with the indication of hypertrophy of the tonsils, abnormal tonsil size, recurrent tonsillitis or previous tonsillitis.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: candidate for planned tonsillectomy with tonsil hypertrophy indication, abnormal tonsil size, recurrent tonsillitis or previous tonsillitis, history of drug abuse before surgery. And exclusion criteria: history of any allergy to opioids, codeine, acetaminophen, aspirin, NSAID. Any contraindications for the use of NSAIDs (such as stomach ulcers, asthma, angioedema, nasal polyps);

Intervention groups
Patients in group O will receive quick-release oxycodone tablets 5 mg (Faran Shimi, Iran) and in group M, meloxicam tablets 15 mg (Razak, Iran) orally 60 minutes before the start of surgery.

Main outcome variables
The intensity of pain after surgery, the amount of painkillers used, the incidence of pain after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230926059532N1**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date
2023-10-14, 1402/07/22

Registrant information

Name
Maryam Montazami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-20, 1402/07/28

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison the effect of oral oxycodone Vs oral meloxicam on pre-emptive control of postoperative pain after tonsillectomy in adults

Public title

Comparison the effect of oral oxycodone Vs oral meloxicam on pre-emptive control of postoperative pain after tonsillectomy in adults

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient willingness to participate in the study and gain informed consent candidate for planned tonsillectomy with the indication of hypertrophy of tonsils, abnormal tonsil size, recurrent tonsillitis or previous tonsillitis Age over 18 years BMI between 18 and 35

Exclusion criteria:

Patient dissatisfaction Age below 18 years History of bleeding diseases Renal failure Liver failure Chronic heart failure History of drug abuse before surgery History of long-term use of analgesics and NSAIDs regardless of the reason for its use History of any allergy to opioids, codeine, acetaminophen, aspirin, NSAID Any contraindications to the use of NSAIDs (such as peptic ulcer, asthma, angioedema, nasal polyps) History of obstructive sleep apnea Mental instability Pregnancy History of nasal polyps

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the criteria for entering the study were divided into two intervention and control groups using the block randomization method. Random Elokit software will be used to do this. And patients are selected in groups of 4 based on the time they entered the study and assigned to two study groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Before the operation, adequate explanations and training will be provided to the patients on how to determine the intensity of the pain after the operation using the NRS (Numeric Rating Scale) standard. Patients in group O will receive quick-release oxycodone tablets 5 mg (Faran Shimi, Iran) and in group M, meloxicam tablets 15 mg (Razak, Iran) orally 60 minutes before the start of surgery. The drug under study has been prepared in a numbered paper package and is given to all patients 60 minutes before the start of anesthesia by the associate nurse of the project, who does not know about the study groups, to be swallowed with a little water. All the prepared packages have two pills, one of which is one of the pills under study and the other pill is a placebo, and in terms of appearance, it completely matches with the other pill under study. The packages were prepared and numbered by the project pharmacologist colleague and The discretion of the prescribing nurse is placed. In our study, both the patient and the prescribing nurse were blinded to the prescribed medication. The surgeon and the pain evaluator based on the NRS criterion also do not know the type of drug used by the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of mazandaran of medical sciences

Street address

Mazandaran University of medical sciences, at the begining of Valiasr Highway, Joibar three ways, imam Square,Sari, Mazndaran Province

City

Sari

Province

Mazandaran

Postal code

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Approval date

2022-11-30, 1401/09/09

Ethics committee reference number

IR.MAZUMS.REC.1401.400

Health conditions studied

1

Description of health condition studied

Tonsil hypertrophy

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

Primary outcomes

1

Description

The primary outcome of the comparison study of pain

after surgery (yes/no)

Timepoint

After surgery

Method of measurement

These outcomes are measured by an experienced nurse who does not know the assignment of the studied subjects to each of the two allocation groups. Pain level of patients based on NRS (Numeric Rating Scale)

Secondary outcomes

1

Description

Secondary measurement of patients' pain intensity is based on NRS and the amount of use of painkillers.

Timepoint

The pain level of patients based on NRS in minutes (0, 30, 60, minutes after reaching recovery and then 6, 12 and 24 hours after discharge from recovery) will be asked and recorded.

Method of measurement

These outcomes are measured by an experienced nurse who does not know the allocation of the studied subjects to each of the two allocation groups. If the pain intensity is higher than 4 based on the NRS criteria, the patient is given intravenous acetaminophen one gram with a maximum limit of 4. grams per day and at least 6 hours between two doses, and the number of doses received will be recorded.

Intervention groups

1

Description

Intervention group: Oxycodone rapid release tablet 5 mg (Faran Shimi, Iran) orally 60 minutes before surgery.

Category

Prevention

2

Description

Intervention group: They will receive 15 mg meloxicam tablets (Razak, Iran) orally 60 minutes before surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Buali Sina Hospital

Full name of responsible person

Maryam Motazemi

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Buali Sina Hospital, First of Ghaemshahr road. Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Maryam Montazemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available