Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of the effect of Meloxicam 7.5 mg and Naproxen 250 mg in reducing complications after fully occluded mandibular third molar surgery;a split-mouth study

Protocol summary

Study aim

Comparison of the effect of meloxicam 7.5 and naproxen 250 mg on the reduction of complications after fully occluded mandibular third molar surgery

Design

Clinical trial with parallel groups, double-blind, randomized, phase 3 on 30 patients. Random block allocation randomization list will be prepared using Random allocation software and will be provided to the researcher.

Settings and conduct

Meloxicam 7.5 mg will be administered after surgery on one side of the mandible , and naproxen 250 mg will be prescribed after surgery on the other side of the mandible..This clinical trial study will be performed in a double-blind manner so that blinding will be performed for both patients participating in the study and the statistician.This study will be conducted in Shahrekord University of Medical Sciences in 2022.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients are in the age group of 20 to 35 years and have no history of any systemic diseases, also have good oral hygiene and have the satisfaction to enter the study. Exclusion criteria: Patients who are pregnant, have a history of opioid addiction and analgesia, or have used analgesics 24 hours before surgery, the root of the impacted tooth is in contact with the mandibular nerve, and patients who are willing to enter Do not study or can not be followed during the study.

Intervention groups

Meloxicam 7.5 mg will be administered after surgery on one side of the mandible , and naproxen 250 mg will be prescribed after surgery on the other side of the mandible. In this way, 60 dental surgeries will be evaluated in 30 people. Patients will be evaluated before the surgery by the expressed scales in terms of swelling, pain and trismus

Main outcome variables

It is hoped that using the results of this study can reduce swelling, trismus and especially pain in patients undergoing fully incised mandibular third molar surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220418054585N1**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-17, 1401/04/26**
Update count: **0**

Registration date

2022-07-17, 1401/04/26

Registrant information

Name

Ali Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-07-21, 1401/04/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of Meloxicam 7.5 mg and Naproxen 250 mg in reducing complications after fully occluded mandibular third molar surgery;a split-mouth study

Public title
Comparison effect of Naproxen and Meloxicam after fully occluded mandibular third molar surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients are in the age range of 20 to 35 years Have no history of any systemic disease It also has good oral hygiene Have the consent to enter the study.
Exclusion criteria:
Patients who are pregnant, Has a history of drug addiction and analgesics Have used painkillers 24 hours before the operation The root of the impacted tooth is in contact with the mandibular nerve
Age
From **20 years** old to **35 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Meloxicam 7.5 mg will be administered completely on one side of the mandible completely after surgery, and naproxen 250 mg will be prescribed after maxillofacial surgery on the other side of the mandible. In this way, 60 dental surgeries will be evaluated in 30 people.
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be selected and entered into the study according to the inclusion criteria by simple random sampling. In order to randomly assign individuals to the groups under study, the method of randomization of permutation blocks with a volume of 16 blocks will be used. The randomization list will be prepared by permutation block method using Random allocation software and will be provided to the researcher.
Blinding (investigator's opinion)
Double blinded
Blinding description
This clinical trial study will be performed in a double-blind manner so that blinding will be performed for both patients participating in the study and the statistician. Blinding for patients will be such that naproxen and meloxicam tablets will be available in similar packages and in exactly the same color, and patients will have no knowledge of the content of the intervention received. Also, the information file will be provided to the statistical analyst in the form of groups A and group B, and this person will not have any information about the content of the intervention of groups A and B, which means that all results will be analyzed based on groups A and B and provided to the main researcher. .
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
kashani Blvd , Shahrekord
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Approval date
2022-07-05, 1401/04/14
Ethics committee reference number
IR.SKUMS.MED.REC.1401.018

Health conditions studied

1

Description of health condition studied
Extraction of fully occluded mandibular third molar surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain
Timepoint
12 and 24 hours after surgery,
Method of measurement

The Visual Analogue Scale is used to assess pain before surgery, 12 and 24 hours after. This scale includes derivation from zero to 10. Zero means no pain and 10 means too much pain, forcing the person to rest at home. The patient will be informed about the pain scale before surgery and will be asked by phone 12 and 24 hours after surgery.

2

Description
swelling
Timepoint
2 and 7 days after surgery
Method of measurement
. To evaluate swelling before surgery, 2 and 7 days later, Gabka and Matsura methods are used. will be. In this method, the distance between the outer corner of the eye and the mandibular angle, between the tragus and the outer corner of the mouth, and between the tragus and the soft tissue of the pogunion is measured in millimeters. Then the average of these three numbers is calculated and inflation is obtained

3

Description
trismus
Timepoint
2 and 7 days after surgery
Method of measurement
A ruler will be used to check for trismus before surgery, 2 and 7 days after. The distances between the upper and lower centers before and after the operation are measured using a ruler..

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After the third molar tooth surgery in one side of the mandible, meloxicam 7.5 mg will be prescribed, and after the impacted tooth surgery on the other side of the mandible, naproxen 250 mg. Will be prescribed. In this way, 60 dental surgeries will be evaluated in 30 people.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord Dental School
Full name of responsible person
Dr Seyed Masih Mousavi Seresht
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Sponsors / Funding sources

1

Sponsor
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Ali Karimi
Position

student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Patient information will be provided in the form of tables and graphs while maintaining confidentiality.

When the data will become available and for how long
The start of access to information will be after analyzing the information and confirming the scientific references.

To whom data/document is available
Due to the therapeutic role of the study, therapists and researchers will be allowed to access the data.

Under which criteria data/document could be used
Doctors and dentists, statistical consultants of articles, scientific journals can submit applications.

From where data/document is obtainable
1)A2022karimi@gmail.com 2)smmoosavis@gmail.com

What processes are involved for a request to access data/document
After verifying the identity of the applicant will be provided to them.

Comments