

# 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)

##### Phone

+98 31 3372 4342

##### Email address

a2022karimi@gmail.com

##### 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

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Sharekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

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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 pogonion 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**

#### **Name of organization / entity**

Shahre-kord University of Medical Sciences

#### **Full name of responsible person**

Dr Sfandiyar Heydariyan

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NO 2, University Headquarters, Kashani Blvd,

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#### **Email**

vcrt@skums.ac.ir

### **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 scientific inquiries

### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Seyed Masih Mousavi Seresht  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Seyed Masih Mousavi Seresht  
**Position**

## 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