

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of Meloxicam and Profen in duration of analgesia after mandibular impacted third molar surgery

Protocol summary

Study aim

Comparison of the effect of meloxicam with ibuprofen on the duration of analgesia after mandibular impacted third molar surgery

Design

Clinical trial with parallel, double-blind, randomized groups, phase 3 on 15 patients

Settings and conduct

The study was performed in the surgery department of the School of Dentistry of the Islamic Azad University and a private office and the patient and the researcher and examiner were kept blind.

Participants/Inclusion and exclusion criteria

Age range 17 to 35 years Having bilateral impacted wisdom teeth Absence of systemic disease Absence of inflammation

Intervention groups

Half an hour to an hour before the start of surgery, the patient was randomly given Meloxicam and Profane once.

Main outcome variables

Duration of analgesia after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170307032929N3**

Registration date: **2020-09-18, 1399/06/28**

Registration timing: **retrospective**

Last update: **2020-09-18, 1399/06/28**

Update count: **0**

Registration date

2020-09-18, 1399/06/28

Registrant information

Name

Fina Navi

Name of organization / entity

Islamic Azad University Tehran Dental Branch

Country

Iran (Islamic Republic of)

Phone

+98 912 201 5179

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f_navi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-04-09, 1399/01/21

Actual recruitment start date

2019-10-23, 1398/08/01

Actual recruitment end date

2020-08-12, 1399/05/22

Trial completion date

2020-08-12, 1399/05/22

Scientific title

Comparison of the Effectiveness of Meloxicam and Profen in duration of analgesia after mandibular impacted third molar surgery

Public title

Effect of Meloxicam and Profen in analgesia after mandibular impacted third molar surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients in the age range of 17 to 35 Requires bilateral surgery of mandibular impacted third molar

Exclusion criteria:

Acute or chronic inflammation Taking other medications

Pregnancy Contraindication of study drugs for patient
Systemic problems

Age

From **17 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **15**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The mandibular quadrants were divided into case and control groups, and one of the two test pills was randomly given to each individual during two visits for surgery on each side of the mandible. In each sample, meloxicam and profen were given one by one. In this way, if in the first patient we gave meloxicam for the left surgery, in the second patient we gave meloxicam for the right surgery.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study was performed on 15 people in the age range of 17 to 35 years with complete satisfaction. They were informed that two approved painkillers were being used. The surgeon, examiner, and patient were not aware of the name of the drug, and the drug was taken out of the coded box by the assistant and given to the patient. The amount of pain was noted on a piece of paper during the hours specified by the patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Islamic Azad University of
Medical Sciences

Street address

Unit 3.No. 23. Abbasi Alley,Shahran Ave, Tehran Town

City

Tehran

Province

Tehran

Postal code

1478676641

Approval date

2019-07-14, 1398/04/23

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.030

Health conditions studied

1

Description of health condition studied

Removal of impacted mandibular third molar

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

Duration of analgesia

Timepoint

The patient is given medicine half an hour before the start of surgery and the pain is recorded 2, 4, 6, 10, 15 hours after the surgery.

Method of measurement

In the study of the effect of meloxicam and profen on duration of analgesia after mandibular impacted third molar surgery, the method of measuring the variable can be visual analog scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient was randomly given a 15 mg Meloxicam tablet half an hour before the start of surgery, and the patients were told they can use an volatile drug such as acetaminophen if they had severe pain so in this group that use volatile dug our study would end.

Category

Treatment - Surgery

2

Description

Control group: The patient was randomly given a 400 mg Profen tablet half an hour before the start of surgery, and the patients were told they can use an volatile drug such as acetaminophen if they had severe pain so in this group that use volatile dug our study would end

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Islamic Azad University of Medical Science
Dental Branch Faculty of dentistry-Department of Su

Full name of responsible person

Shima Naderkhani

Street address

No. 23, Abbasi Alley, Shahrn Ave, Tehran Town

City

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2

Recruitment center

Name of recruitment center

4th Floor, Karoon Building, West Bolvar Ferdos Ave ,
Tehran

Full name of responsible person

Shima Naderkhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Islamic Azad University,
Tehran Dental Branch

Full name of responsible person

Arash Azizi

Street address

No. 9, Pasdaran St., 9th Neyestan, Tehran Town

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1946853314

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Email

drarashazizi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Islamic Azad University,
Tehran Dental Branch

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Fina Navi

Position

Oral and Maxillofacial surgeon

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shima Naderkhani

Position

Dentistry Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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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

Participants' data file, consent form, number one and two information form, research method, statistical analysis and related tables will be shared.

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions will also be available, as well as people working in industry

Under which criteria data/document could be used

Access to information forms is only possible for researchers in this field

From where data/document is obtainable

Researcher Ms.Shima Naderkhani, contact number: 09128509183, address: No. 23, Abbasi Alley, Shahrān Ave, Tehran Town Email: www.naderkhani.shima@gmail.com

What processes are involved for a request to access data/document

Request by email and the result will be communicated to them as soon as possible

Comments