Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 impcted 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
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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 bilatral 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 Islamc Azad University of Medical Science Dental Branch Faculty of dentistry-Department os Su

Full name of responsible person
Shima Naderkhani

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2

Recruitment center

Name of recruitment center
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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

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Position
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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
Reasearcher Ms.Shima Naderkhani, contact number: 09128509183, address: No. 23, Abbasi Alley, Shahran 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 commiunicated to them as soon as possible
Comments