Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Premedication Using Ibuprofen and Meloxicam on the success rate of Inferior Alveolar Nerve Block in mandibular first molars with symptomatic Irreversible Pulpitis

Protocol summary

Study aim
Comparison of Premedication Using Ibuprofen and Meloxicam on success rate of Inferior Alveolar Nerve Block in mandibular first molars with symptomatic Irreversible Pulpitis

Design
A clinical trial with parallel intervention groups, double-blind, randomized, on 165 patients. The sampling method is random. Randomization using a table of random numbers is the Random Allocation Software.

Settings and conduct
Random sampling will be done among the patients referred to the endodontics department of Tabriz Faculty of Dentistry who are eligible for the study. Patients are randomly assigned to one of the groups. One hour before the start of the treatment, Ibuprofen 800 mg capsule will be used in group A, Meloxicam 15 mg capsule in group B, and placebo capsule (lactose powder) in group C. Before starting the treatment, their pain level is recorded. Then, all patients are under the same anesthesia. The success or failure of lip anesthesia is recorded. During the treatment, the amount of pain is determined. The patient is aware of the existence of several types of treatment, but he does not know which group he is in, and the researcher is not aware of the type of medicine.

Participants/Inclusion and exclusion criteria
Including: First molar teeth of the lower jaw with the diagnosis of symptomatic irreversible pulp inflammation, willingness to participate in the study Excluding: Signs of radiolucency around the apex of the roots, use of painkillers within 12 hours before treatment, having a full crown or partial necrosis in the studied tooth, teeth with previous root treatment, advanced periodontal disease

Intervention groups
Intervention 1: Use Ibuprofen 800 mg capsule one hour before the treatment Intervention 2: Use Meloxicam 15 mg capsule one hour before treatment Placebo: Use a lactose powder capsule one hour before treatment

Main outcome variables
The amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220909055923N1**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date
2022-09-10, 1401/06/19

Registrant information

Name
Behzad Sheikhfaal

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 912 533 5279

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-10, 1401/06/19

Expected recruitment end date
2022-10-10, 1401/07/18

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Premedication Using Ibuprofen and Meloxicam on the success rate of Inferior Alveolar Nerve Block in mandibular first molars with symptomatic Irreversible Pulpitis

Public title
The effect of Ibuprofen and Meloxicam on dental anesthesia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Systemically healthy A history of spontaneous, or severe pain during cold testing Age 20-40 years
Exclusion criteria:
Suffering from systemic diseases Allergy to one of the following: Lidocaine, Epinephrine, NSAIDs, Dexamethasone, Caffeine Suffering from asthma, coagulation disorder, nervous and mental disorder, diseases of immune system defects Pregnancy and breastfeeding for women Allergy to the anesthetic Having a heart pace-maker
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **165**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sampling will be done among the patients referred to the endodontics department of Tabriz Faculty of Dentistry who are eligible for the study. The randomization method is simple and its unit is individual. Our tool for randomizing a table of random numbers. Based on this, the type of treatment is marked with code A (Ibuprofen), B (Meloxicam), and code C (placebo/powdered lactose) and placed inside sealed envelopes. Then the envelopes are placed in a bag and mixed. Then it is randomly selected from the bag and treatment is given to the patient by observing the code. None of the patients will be informed about the treatment of another patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double-blind, and the patients do not know about the type of group they will be included in. A researcher will not know about the type of medicine. Patients are aware of the existence of several types of treatment, but they do not know which group they belong to.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Golgasht St., Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2022-08-29, 1401/06/07
Ethics committee reference number
IR.TBZMED.REC.1401.495

Health conditions studied

1

Description of health condition studied
Dental caries
ICD-10 code
K02
ICD-10 code description
Dental caries

Primary outcomes

1

Description
The amount of pain
Timepoint
Before and during root canal treatment
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Ibuprofen capsule 800 mg (Reha Pharmaceuticals) will be used one hour before root canal treatment. Before starting the treatment, their pain level is recorded. One hour after the oral administration of the capsule, all patients are under lidocaine and epinephrine anesthesia. 15 minutes later, the success or failure of lip anesthesia is recorded. During the treatment, the amount of pain is determined in groups.

Category
Treatment - Drugs

2

Description
Intervention group 2: Meloxicam 15 mg capsules (Iran Daru Pharmaceuticals) will be used one hour before the root canal treatment. Before starting the treatment, their pain level is recorded. One hour after the oral administration of the capsule, all patients are under lidocaine and epinephrine anesthesia. 15 minutes later, the success or failure of lip anesthesia is recorded. During the treatment, the amount of pain is determined in groups.

Category
Treatment - Drugs

3

Description
Placebo group: A lactose powder capsule (prepared by the pharmacist) will be used one hour before root canal treatment. Before starting the treatment, their pain level is recorded. One hour after the oral administration of the capsule, all patients are under lidocaine and epinephrine anesthesia. 15 minutes later, the success or failure of lip anesthesia is recorded. During the treatment, the amount of pain is determined in groups.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz
Full name of responsible person
Mohammad Forough Reyhani
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Golgasht St., Tabriz University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Forough Reyhani
Position
Professor
Latest degree
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Data Dictionary
Not applicable