

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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 Sheikhaal

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 533 5279

Email address

b.sh11399@gmail.com

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

Street address

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 44 3344 4598

Email

moh_reyhani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mozghan Kachuei

Street address

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 44 3344 4598

Email

moh_reyhani@yahoo.com

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

Specialist

Other areas of specialty/work

Dentistry

Street address

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province
East Azarbaijan
Postal code
5166614711
Phone
+98 44 3344 4598
Email
moh_reyhani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Forough Reyhani
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Golgasht St., Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 44 3344 4598
Email
moh_reyhani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Forough Reyhani
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Golgasht St., Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 44 3344 4598
Email
moh_reyhani@yahoo.com

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