Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of pain after mandibular impacted third molar surgery following pregabalin and acetaminophen

Protocol summary

Study aim
Evaluation of pain after mandibular impacted third molar surgery following pregabalin and acetaminophen

Design
A clinical trial with the parallel intervention group, double blind, randomized on 32 patients. The sampling method is random. The randomization method is simple and with a table of random numbers.

Settings and conduct
Among the patients referred to the Department of Oral and Maxillofacial Surgery of Tabriz Faculty of Dentistry, who are present for the surgery of bilateral mandibular impacted third molar teeth, participate in the study. Patients are randomly assigned to one of the groups. The first group received acetaminophen 650 mg and the second group received pregabalin 150 mg with 100 cc of water. The surgery is performed on the right tooth. One month after the first surgery, the drugs will be changed and the opposite tooth surgery will be performed in the same way by the same surgeon. Patients will record their post-surgery pain level every two hours for 24 hours based on VAS in the prescribed table. The evaluator and the patient are not aware of the type of drug used.

Participants/Inclusion and exclusion criteria
Include criteria: Candidates for surgery on the third molar of the mandible on both sides that are of the same level of difficulty. Exclude criteria: History of chronic use of pregabalin, history of pain in the mandibular molar region

Intervention groups
Intervention: use of pregabalin 150 mg one hour before surgery Control: use of acetaminophen 650 mg one hour before surgery

Main outcome variables
The amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220316054314N1**
Registration date: **2022-07-08, 1401/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-08, 1401/04/17**
Update count: **0**

Registration date
2022-07-08, 1401/04/17

Registrant information

Name
Amir Alizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3656 9686

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amir1994alizade@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-04, 1401/04/13

Expected recruitment end date
2022-07-30, 1401/05/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of pain after mandibular impacted third molar surgery following pregabalin and acetaminophen

Public title
Investigation of pain after implanted tooth surgery following taking pregabalin and acetaminophen
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18-35 years old Candidate for surgery on the hidden third molar of the lower jaw on both sides
Exclusion criteria:
History of diabetes controlled by oral medications Using Corticosteroid History of using drug History of using chronic NSAID drugs History of chronic use of pregabalin or sedative drugs History of painkiller consumption in the last 24 hours Psychiatric disorder History of bone disease History of bilateral mandibular molar pain
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patients on both sides need mandibular third molar surgery.
Randomization (investigator's opinion)
Randomized
Randomization description
The method of random sampling is among the people who refer to the maxillofacial surgery department of Faculty of Dentistry in Tabriz. The randomization method is simple and individual. Our tool for randomizing a table of random numbers. Also, the allocation of treatment to patients will be done randomly. In such a way that the type of treatment is specified with the code A (acetaminophen) and B (pregabalin) and will be placed inside the sealed envelopes; Then the envelopes will be placed in a bag and mixed. Then it will be randomly removed from the bag and after seeing the code, the treatment will be given to the patient. None of the patients will be informed about the type of treatment of another patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medicines will be coded in similar containers with A and B codes. The evaluator who will follow the patients and record their pain level and painkillers will not be aware of the type of drugs. Also, the patient is aware of the existence of two types of drugs, but they will not be aware of the type of drug in each surgery.
Placebo
Not 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
2nd Floor, Central Building No. 2,Tabriz University of Medical Sciences, Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2022-06-27, 1401/04/06
Ethics committee reference number
IR.TBZMED.REC.1401.290

Health conditions studied

1

Description of health condition studied
Impacted teeth
ICD-10 code
K01.1
ICD-10 code description
Impacted teeth

Primary outcomes

1

Description
The amount of pain
Timepoint
Up to 24 hours after surgery, once every two hours
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 150 mg of pregabalin with 100 cc of water will be given to the patient one hour before the

mandibular third molar extraction surgery. Up to 24 hours after surgery, the patient will record the level of pain every two hours based on the VAS on the designated table.

Category

Treatment - Drugs

2

Description

Control group: 650 mg of acetaminophen with 100 cc of water will be given to the patient one hour before the mandibular third molar extraction surgery. Up to 24 hours after surgery, the patient will record the level of pain every two hours based on the VAS on the designated table.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Dentistry, Tabriz

Full name of responsible person
Farrokh Farhadi

Street address
Tabriz University of Medical Sciences, Golgasht St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mozhgan Kechoui

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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
Farrokh Farhadi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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