

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of pain relief efficacy of pre operative intravenous ketorolac and oral pregabalin in patients undergoing mandibular fracture surgery

Protocol summary

Study aim

The aim of this study is to compare the pain relief effects of intravenous ketorolac and oral pregabalin in patients undergoing mandibular fracture surgery.

Design

Clinical trial with a control group, in two parallel groups, with a sample size of 60 patients, without blindness

Settings and conduct

This study will perform among patients referred to Emam Reza hospital in Tabriz with unilateral mandibular fracture. Before surgery, patients will be randomly divided into two groups. In group 1 (Control), a 30-mg dose of intravenous ketorolac (Caspian Pharmaceutical Company, Iran) will be injected one hour before induction of anesthesia. In group 2 (Intervention), a 150-mg dose of oral pregabalin (pharmaceutical company Jalinas, Iran) will be prescribed one hour before induction of anesthesia. Then, the severity of pain was recorded and compared immediately after consciousness and 2, 4, 6, 8, 12, 24 hours after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with unilateral fracture of mandible in body and angle region, that have not been fracture for more than 2 weeks. Exclusion criteria: Addicted patients

Intervention groups

In group 1 (Control), a 30-mg dose of intravenous ketorolac (Caspian Pharmaceutical Company, Iran) will be injected one hour before induction of anesthesia. In group 2 (Intervention), a 150-mg dose of oral pregabalin (pharmaceutical company Jalinas, Iran) will be prescribed one hour before induction of anesthesia.

Main outcome variables

Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150628022951N10**

Registration date: **2019-07-22, 1398/04/31**

Registration timing: **prospective**

Last update: **2019-07-22, 1398/04/31**

Update count: **0**

Registration date

2019-07-22, 1398/04/31

Registrant information

Name

milad Ghanizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5921

Email address

milad.ghanizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain relief efficacy of pre operative intravenous ketorolac and oral pregabalin in patients undergoing mandibular fracture surgery

Public title

Preoperative administration of oral pregabalin for reducing pain in patients with mandibular fractures

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with unilateral mandibular fracture in the body and angle region, with fracture occurring not more than two weeks ago

Exclusion criteria:

Addicted patients

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 60 patients referred to Emam Reza hospital in Tabriz with unilateral mandibular fracture, will be selected by simple random sampling and included in the study. Then a code will be assigned to each patient and they will be divided into two equal groups with a simple randomization method and by a person not aware of the study objectives by using RandList software. Each patient will be receive special intervention for that group.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-05-28, 1398/03/07

Ethics committee reference number

IR.TBZMED.REC.1398.206

Health conditions studied**1****Description of health condition studied**

Pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes**1****Description**

Pain Intensity

Timepoint

Immediately after consciousnesses and 2, 4, 6, 8, 12, 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Intra-venous injection of a 30-mg dose of ketorolac (Caspian Pharmaceutical Company, Iran) one hour before induction of anesthesia.

Category

Treatment - Drugs

2**Description**

Intervention group : Oral administration of a 150 mg pregabalin tablet (Jalinas Pharmaceutical Company, Iran) one hour before induction of anesthesia

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz University of Medical Sciences

Full name of responsible person

Milad Ghanizadeh

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166615739

Phone

+98 41 3335 9680

Fax**Email**

milad.ghanizadeh@gmail.com

Web page address

<https://www.tbzmed.ac.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolgasem Joyban

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4658

Email

researchteam.tbzmed@gmail.com

Web page address

<https://www.tbzmed.ac.ir>

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

Javad Yazdani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4658

Email

Ja_yazdani@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Javad Yazdani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

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Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4658

Email

Ja_yazdani@yahoo.com

Web page address

<https://www.tbzmed.ac.ir>

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

Tabriz University of Medical Sciences

Full name of responsible person

Milad Ghanizadeh

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 5921

Fax

+98 41 3335 9680

Email

milad.ghanizadeh@gmail.com

Web page address

<https://www.tbzmed.ac.ir>

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

Demographic information of patients and data related to the outcomes of the study (pain intensity) will be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Sharing data for meta-analysis

From where data/document is obtainable

Please contact Dr. Milad Ghanizadeh by e-mail: Milad.ghanizadeh@gmail.com

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

After ensuring that your claim is true, these data will be sent to you.

Comments