

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Analgesic Efficacy of intravenous and intranasal ketorolac in patients undergoing mandibular fracture surgery

Protocol summary

Study aim

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

Design

Clinical trial with a sample size of 54 patients in two parallel groups, without blindness

Settings and conduct

This study will perform among patients referred to Emam Reza Hospital in Tabriz with unilateral mandibular fracture. After surgery, patients are randomly divided into two groups. In the first group, 30 ml intravenous ketorolac ampule will be injected every 8 hours. In the second group, the 15% intranasal ketorolac spray will be used every 6 hours. Then, the severity of pain in patients will be recorded and compared 2, 4, 6, 8, 12, 24, 36 and 48 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 3 months. Exclusion criteria: Addicted patients

Intervention groups

In the first group, patients undergoing mandibular fracture surgery, receive analgesic ampoule's of ketorolac. In the second group, patients receive ketorolac intra nasal spray.

Main outcome variables

Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150628022951N8**

Registration date: **2018-09-14, 1397/06/23**

Registration timing: **prospective**

Last update: **2018-09-14, 1397/06/23**

Update count: **0**

Registration date

2018-09-14, 1397/06/23

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

2018-09-22, 1397/06/31

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Analgesic Efficacy of intravenous and intranasal ketorolac in patients undergoing mandibular fracture surgery

Public title

Effect of ketorolac Spray on Reducing Pain in Patients with mandible Fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with unilateral fracture of mandible in body and angle region, Which has not been fractured for more than 3 months

Exclusion criteria:

Addicted patients

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used. Each person will be assigned a code, and according to the random number table, each person will be placed in a 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

2018-03-02, 1396/12/11

Ethics committee reference number

IR.TBZMED.REC.1396.1270

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

2, 4, 6, 8, 12, 24, 36 and 48 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous injection of 30 mg ketorolac ampoule every 8 hours

Category

Treatment - Drugs

2

Description

Intervention group: Intranasal 15% ketorolac spray every 6 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Farhad Nojan

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
Research deputy of Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 4658
Email
researchteam.tbzmed@gmail.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
Javad Yazdani
Position
Associate 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
Farhad Nojan
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

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farhad Nojan
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

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. Farhad Nojan by e-mail: researchteam.tbz@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