Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

Comparison of pain relief efficacy of pre empetive intravenous ketorolac and oral pregabalin in patients undegoing 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

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Iran (Islamic Republic of)

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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 empetive intravenous ketorolac and oral pregabalin in patients undegoing 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

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Sponsors / Funding sources

1

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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
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Javad Yazdani
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Professor
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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