

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of pain relief effect of various doses of intravenous ketorolac at different times of mandibular fracture surgery

Protocol summary

Summary

In this clinical trial, 50 patients referred to Imam Reza Hospital with unilateral fracture of the mandible and indications for intra-oral Open Reduction treatment will be randomly selected and randomly divided into 5 groups. In this double-blind study, the surgeon and patients will be blinded to the study. Inclusion criteria: Patients with unilateral mandibular fracture Exclusion criteria: Duration of surgery more than 2 hours; Drug abuse by patients; History of systemic disease, History of drug allergy In Group A, immediately before induction of anesthesia a ketorolac 30 mg ampule, in Group B, immediately before induction of anesthesia a ketorolac 60 mg ampule, in Group C, immediately before the completion of surgery a ketorolac 30 mg ampule, in group D, immediately after the completion of surgery a ketorolac 60 mg ampule will be injected intravenously. It will not be injected for the Group E. After consciousness of the patient, intensity of pain(primary outcome variable) whit a numerical scale VAS at 0, 2, 4, 6, 12, 24 hours will be measured. Data from the study will be analyzed using appropriate statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031322951N4**

Registration date: **2017-04-14, 1396/01/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-14, 1396/01/25

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

Tabriz University of Medical sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain relief effect of various doses of intravenous ketorolac at different times of mandibular fracture surgery

Public title

Comparison of pain relief effect of various doses of intravenous ketorolac at different times of mandibular fracture surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with unilateral mandibular fracture Exclusion criteria: Duration of surgery more than 2 hours; Drug abuse by patients; History of systemic disease, History of drug allergy

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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

City
Tabriz

Postal code

Approval date
2016-08-29, 1395/06/08

Ethics committee reference number
IR.TBZMED.REC.1395.639

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
R52.9

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description

Pain Intensity

Timepoint
0, 2, 4, 6, 12, 24 hours After surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
In Group A(Intervention), immediately before induction of anesthesia a ketorolac 30 mg ampule will be injected intravenously

Category
Treatment - Drugs

2

Description
In Group B(Intervention), immediately before induction of anesthesia a ketorolac 60 mg ampule will be injected intravenously

Category
Treatment - Drugs

3

Description
In Group C(Intervention), immediately before the completion of surgery a ketorolac 30 mg ampule will be injected intravenously

Category
Treatment - Drugs

4

Description
In Group D(Intervention), immediately after the completion of surgery a ketorolac 60 mg ampule will be injected intravenously

Category
Treatment - Drugs

5

Description
In Group E(Control), Ketorolac ampule will not be injected

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences

Full name of responsible person

Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research deputy of Tabriz University of Medical Sciences

Full name of responsible person
Dr. Saeed Nezafati

Street address
Research deputy of Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research deputy of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Sina Mirinejad

Position
Resident of Oral and Maxillofacial Surgery

Other areas of specialty/work

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Dr. Sina Mirinejad

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Resident of Oral and Maxillofacial Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty