

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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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