

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Effect of intravenous ketorolac on postoperative pain in mandibular fracture surgery

#### Protocol summary

##### Summary

(1) Objectives: The aim of this paper was to measure the analgesic effect of intravenous ketorolac during the immediate postoperative period in recovery room for postoperative pain relief as well as their side effects in patients undergoing mandibular fracture surgery to assess the analgesic effect and the need for opioids. (2) Design: This is a double-blind randomised clinical trial study, that severity of pain was evaluated by visual analogue scale and the amount of opioid consumption after surgery. (3) Setting and conduct: A total of 50 adult patients were selected for this randomized controlled trial. All subjects were divided into two groups to receive ketorolac or placebo. The anesthesiologist administered 30 mg of ketorolac intravenously end of the operation in post anesthesia care unit immediately upon the onset of pain in study group and in the control group patients received placebo with 1cc of distilled water solution. (4) Participants including major eligibility criteria: Subjects who had systemic disease and history of drug consumption and lack of signed informed consent will be excluded from the study sample. (5) Intervention: Patients in the study group will be received an intravenous "Ketorolac" 30 mg bolus for 30 sec end of the operation in post anesthesia care unit immediately upon the onset of pain and the placebo group will receive " Distilled Water " as same bolus volume in a 30-sec intravenous infusion. (6) main outcome measures: After surgery the patients were monitored for up to 4 hours in the recovery room and pain intensity (VAS 100-mm) is measured by a person who was uninformed about case and control groups every 5 min. Post-operative complications will be asked in the questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201607271674N13**

Registration date: **2016-08-06, 1395/05/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-06, 1395/05/16

##### Registrant information

###### Name

Hamid Reza Eftekharian

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3636 4001

###### Email address

eftekhahr@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Supported by Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

##### Expected recruitment start date

2015-04-21, 1394/02/01

##### Expected recruitment end date

2016-04-22, 1395/02/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of intravenous ketorolac on postoperative pain in mandibular fracture surgery

## Public title

Treatment of postoperative pain with intravenous ketorolac in mandibular fracture surgery

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria included 16-47 year old patients whom were scheduled to undergo mandibular fractured surgy; Subjects who had systemic disease and history of drug consumption; history of drug allergic reaction; hepatic and renal dysfunction and lack of signed informed consent will be excluded from the study sample

## Age

From **16 years** old to **47 years** old

## Gender

Both

## Phase

2

## 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 Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz

##### City

Shiraz

##### Postal code

71345-1978

#### Approval date

2015-06-14, 1394/03/24

#### Ethics committee reference number

IR.SUMS.REC.1394.55

## Health conditions studied

### 1

#### Description of health condition studied

Acute pain

#### ICD-10 code

R52.0

#### ICD-10 code description

Acute pain

## Primary outcomes

### 1

#### Description

Intensity of postoperative pain

#### Timepoint

Immediately after surgery to 4 hours after surgery each 5 min.

#### Method of measurement

VAS

### 2

#### Description

Use of narcotic (Pethedin) after surgery for postop. pain management

#### Timepoint

To 4 hours after surgery

#### Method of measurement

Nursing reports

## Secondary outcomes

### 1

#### Description

post-operative complications of Ketorolac

#### Timepoint

Immediately after surgery to 4 hours after surgery

#### Method of measurement

Nursing reports

## Intervention groups

### 1

#### Description

Patients in the interventional group (first group) will be received an intravenous "Ketorolac" 30 mg for 30 Sec. end of the operation in post anesthesia care unit immediately upon the onset of pain

#### Category

Treatment - Drugs

### 2

#### Description

Patients in the the second group will receive " placebo" as same bolus volume of " Distilled Water " in a 30-Sec. intravenous infusion end of the operation in post anesthesia care unit immediately upon the onset of pain

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shiraz Rajaei Hospital

**Full name of responsible person**

Hamid Reza Eftekharian

**Street address**

Shiraz University Of Medical Sciences, Shiraz Rajaei Hospital, Chamran Blvd., Shiraz

**City**

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

**Full name of responsible person**

Sayed Basir Hashemi

**Street address**

Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-Chancellery of Research and Technology, Shiraz 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**

School of Dentistry, Shiraz University of Medical sciences

**Full name of responsible person**

Hamid Reza Eftekharian

**Position**

Associate Professor of Anesthesiology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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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*