# 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 analoug 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 ketoroloc or placebo. The anesthesiologist administered 30 mg of ketoroloc intravenously end of the operation in post anesthesia care uint 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 "Ketoroloc" 30 mg bolus for 30 sec end of the operation in post anesthesia care uint 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**

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**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 Ketoroloc
**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 "Ketoroloc" 30 mg for 30 Sec. end of the operation in post anesthesia care uint 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 uint 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

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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

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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*