Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 71 3636 4001

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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

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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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