Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of Analgesic Effect of Ketorolac in Intravenous Injection and when Added to Lidocaine in Bier Block in Surgery for Traumatic Upper Extremity Injuries

Protocol summary

Summary

Objective: To compare the analgesic effect of intravenous ketorolac added to lidocaine in Bier block in the patients undergoing surgery for traumatic upper extremity injuries. Research Design: Conduction of a randomized, clinical trial Inclusion criteria: patients aged 20 to 60 years; patients undergoing orthopedic surgery for traumatic injuries of upper extremity; eligible for Bier block; ASA I-II; duration of the surgery will be less than 90 minutes; Patients patient's mental ability to collaborate and answered the questions. Exclusion criteria: Long-term use of analgesics (including opioid and non-narcotic); depression; Uncontrolled seizures; peripheral nerves diseases ;sensitivity to the study drugs; renal failure; lack of glucose-6-phosphate dehydrogenase; cardiovascular problems and infection in the injured limb; signs of nerve damage in the injured extremities; liver failure. Interventions: In this study 96 patients with traumatic injury to the upper extremity ketorolac both intravenous systemic and topical added to lidocaine in the Bier block. Patients randomly divided into 3 groups of 32: Distilled water (DW) group: 3 mg / kg lidocaine 5.0 percent in 5 ml of distilled water solution for Bier blocks intravenous (systemic). Topical ketorolac group (RK): 3 mg / kg lidocaine 5.0 percent + 30 mg ketorolac as Bier block and 5 ml of distilled water for intravenous (systemic). Ketorolac group venous (IVK): 3 mg / kg lidocaine 5.0 per cent as Bier block solution and 5 ml distilled water contains 30 mg of ketorolac for intravenous (systemic). Pain intensity will be compared with NRS perioperative, the amount of pain medication needed during the first 24 hours after the operation, the first request for analgesics after the operation and administration of ketorolac and opioid-induced side effects will be investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031419470N20**
Registration date: **2016-04-26, 1395/02/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-26, 1395/02/07

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Analgesic Effect of Ketorolac in Intravenous Injection and when Added to Lidocaine in Bier Block in Surgery for Traumatic Upper Extremity Injuries

Public title
Comparison of Analgesic Effect of Ketorolac in Intravenous Injection and when Added to Lidocaine in Blocks in the Orthopedic Surgeries.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients aged 20 to 60 years; patients undergoing orthopedic surgery for traumatic injuries of upper extremity; eligible for Bier block; ASA I-II; duration of the surgery will be less than 90 minutes; Patients patient's mental ability to collaborate and answered the questions. Exclusion criteria: Long-term use of analgesics (including opioid and non-narcotic); depression; Uncontrolled seizures; peripheral nerves diseases ;sensitivity to the study drugs; renal failure; lack of glucose-6-phosphate dehydrogenase; cardiovascular problems and infection in the injured limb; signs of nerve damage in the injured extremities; liver failure.

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Shiraz University Of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences, Zand Street

City
Shiraz

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
IR.SUMS.Med.RED.1394.19

Health conditions studied

1

Description of health condition studied
Orthopaedic Surgery

ICD-10 code
M96.6

ICD-10 code description
Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate

Primary outcomes

1

Description
Analgesia prioperatively and post operatively

Timepoint
Every 10 min in the operating room and every 15 min in the recovery ,every one hour at the six first hour in the ward , every two hour after six to 12 hours and every 4 hour until 24 hour

Method of measurement
NRS

Secondary outcomes

1

Description
Patient satisfaction

Timepoint
24 hours after surgery

Method of measurement
Questionaire

Intervention groups

1

Description
Distilled water (DW) group: 3 mg / kg lidocaine 5.0 per cent in 5 ml of distilled water solution for Bier block intravenous (systemic).

Category
Treatment - Drugs

2

Description

Topical ketorolac group (RK): 3 mg / kg lidocaine 5.0 percent + 30 mg ketorolac as Bier block and 5 ml of distilled water for intravenous (systemic).

Category

Treatment - Drugs

3

Description

Ketorolac group venous (IVK): 3 mg / kg lidocaine 5.0 per cent as Bier block solution and 5 ml distilled water contains 30 mg of ketorolac for intravenous (systemic).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Maryam Ghadimi

Street address

Chamran Blv, Chamran Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice Chancellor for Research ,Shiraz University of Medical Sciences-7th floor-Central Building of Shiraz University of Medical Sciences , Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Ghadimi

Position

Physician, Anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz anesthesiology and critical care research center

Full name of responsible person

Farzaneh Masihi

Position

English Consultant

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