Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of 0.5% lidocaine local analgesia in combination with and without ketorolac in Bier's Block method in patients with forearm fracture

Protocol summary

Summary

Objective: Clinical trial of comparison the effect of 0.5% lidocaine local analgesia combination with and without ketorolac in Bier's Block method in patients with forearm fracture. Design of the study: randomization using random permuted blocks, convenience sampling, double-blind, single-center, phase II trial. Study population: all patients of forearm fracture with ASA PS I and II. Main inclusion criteria: age limitation 20-50 years; plating candidates of forearm fracture with ASA PS I and II. Main exclusion criteria: positive history of sensitivity to NSAIDs; history of asthma, nasal polyp, bronchospasm or angioedema; history of bleeding of gastric ulcer; medium to severe renal failure; pregnant women; addiction; multiple fractures. Sample size: 90. Interventions: First group: intravenous infusion of 40 miligrams of 0.5% lidocaine in combination with 1 milligram ketorolac plus 1 cc 0.09% normal saline; second group: intravenous infusion of 40 milligrams of 0.5% lidocaine plus 2 milligrams ketorolac; third group: intravenous infusion of 40 milligrams of 0.5% lidocaine in combination with 2 cc 0.09% normal saline(placebo). Intervention time: before the operation. Outcomes: pain during closing of tourniquet; pain after tourniquet deflation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021232520N1**
Registration date: **2017-04-10, 1396/01/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-10, 1396/01/21

Registrant information

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Leila Kadkhudaei
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2016-06-23, 1395/04/03

Expected recruitment end date

2017-06-24, 1396/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of 0.5% lidocaine local analgesia in combination with and without ketorolac in Bier's Block method in patients with forearm fracture

Public title

Comparison the effect of lidocaine local analgesia in combination with and without ketorolac in patients with forearm fracture

Purpose

Supportive

Inclusion/Exclusion criteria
Main inclusion criteria: age limitation 20-50 years; plating candidates of forearm fracture with ASA PS I and II. Main exclusion criteria: positive history of sensitivity to NSAIDs; history of asthma, nasal polyp, bronchospasm or angioedema; history of bleeding of gastric ulcer; medium to severe renal failure; pregnant women; addiction; multiple fractures.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Ethics Committee of Zahedan University of Medical Sciences, Zahedan University of Medical Sciences, Dr.Hesabi Square, Zahedan

City
Zahedan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
IR.ZAUMS.REC.1395.36

Health conditions studied

1

Description of health condition studied
Forearm fracture

ICD-10 code
S52.0, S52

ICD-10 code description
Fracture of forearm

Primary outcomes

1

Description
Pain after tourniquet deflation

Timepoint
half of houre,two houres, four houres, six houres, 12 houres and 24 houres after tourniquet deflation

Method of measurement
VAS Criteria

2

Description
Pain during tourniquet closure

Timepoint
5, 10, 15, 20 and 30 minutes after infusion

Method of measurement
VAS Criteria

Secondary outcomes

empty

Intervention groups

1

Description
First group of intervention: intravenous infusion of 40 miligrams of 0.5% lidocaine in combination with 1 milligram ketorolac plus 1 cc 0.09% normal saline

Category
Treatment - Drugs

2

Description
Second group of intervention: intravenous infusion of 40 milligrams of 0.5% lidocaine plus 2 milligrams ketorolac

Category
Treatment - Drugs

3

Description
Control group: intravenous infusion of 40 milligrams of 0.5% lidocaine in combination with 2 cc 0.09% normal saline(placebo)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali-ebn Abi Taleb Hospital, Zahedan
Full name of responsible person
Leila Kadkhudaei
Street address
Operation room, Zahedan Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan
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Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
Street address
Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan
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Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Zahedan 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
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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