Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of hematoma block with injection of Lidocaine versus hematoma block with injection of Lidocaine plus ketamine on reduction of pain in patients with distal radius fracture

Protocol summary

Study aim

Determining and comparing the effect of block hematoma with lidocaine injection alone compared to lidocaine with ketamineat the onset of analgesia and reduction of pain during reduction and afterwards in patients with distal radius fracture

Design

In this randomized double-blind clinical trial study of phase 3, 60 patients with distal radius fracture underwent simple random assignment in two groups receiving libidocaine injection, only volidocaine with ketamine.

Settings and conduct

This clinical trial study is performed in 1400 in Alzahra hospitals of Isfahan . The study population is patients with distal radius fracture.

Participants/Inclusion and exclusion criteria

Inclusion criteria: distal radius bone fracture that requires reduction by a physician; age older than18 years old; consent to study; absence of trauma in other areas of the body; especially the patient's head; lack of bone abnormalities and previous fractures in the location of the radius bone is insensitivity to lidocaine and ketamine. Exclusion criteria: drug and alcohol addiction; coagulation disorders; psychiatric disorders; liver disorders, epilepsy, hypertension and heart rate less than 55 and patient dissatisfaction to continue the study.

Intervention groups

60 patients with distal radial fractures are assigned in two groups. In the first group, 8 mg of lidocaine 2% and in the second group, 8 mg of lidocaine with 0.5 mg of ketamine is injected.

Main outcome variables

The severity of pain during radius implantation and patient satisfaction are the main outcomes of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200622047874N2**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

marjan zareian jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 6557

Email address

zareiian@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the effect of hematoma block with injection of Lidocaine versus hematoma block with injection of Lidocaine plus ketamine on reduction of pain in patients with distal radius fracture

Public title
Comparison the effect of hematoma block with injection of Lidocaine versus hematoma block with injection of Lidocaine plus ketamine on reduction of pain in patients with distal radius fracture

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Distal radius fracture that requires reduction by a physician Age over 18 years old Satisfaction to enter the study Absence of trauma in other areas of the body, especially the patient's head Absence of bone abnormalities and previous fractures at the site of the radius bone Hypersensitivity to lidocaine and ketamine
Exclusion criteria:
Drug and alcohol addiction Having coagulation diseases Psychiatric disorders Liver disorders Epilepsy Hypertension and heart rate less than 55 Patient dissatisfaction to continue the study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation is performed using random allocation software (RAS). In this software, the total sample size and number of groups are entered into the software. The software output includes a list that distributes the total sample size by number between the two groups. Patients are distributed in two groups according to the list and in order of referral time to complete the sample size in both groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is a double-blind study and patients and researchers are unaware of the type of drug injected to patients. The drugs are prepared and coded by one of the operating room staff in a syringe and given to the researcher for injection.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Hezar Jareeb
City
Isfahan
Province
Isfehan
Postal code
8174673461

Approval date
2018-06-21, 1397/03/31

Ethics committee reference number
IR.MUI.REC.1397.174

Health conditions studied

1

Description of health condition studied
radius fracture

ICD-10 code
S52. 5

ICD-10 code description
radious fracture

Primary outcomes

1

Description
Patients' pain score during manipulation (reduction)

Timepoint
At the time of fracture placement and 1 and 6 hours later

Method of measurement
Visual analog scale (VAS) that divides pain intensity from zero to ten

Secondary outcomes

1

Description
Patient satisfaction

Timepoint
In the 6 hour after fracture placement

Method of measurement

Likert criteria for satisfaction, completely satisfied, satisfied, dissatisfied, dissatisfied and completely dissatisfied

Intervention groups

1

Description
intervention group 1: In this group, block hematoma is performed by injecting 8 ml of 2% lidocaine.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, block hematoma is performed by injecting 8 ml of 2% lidocaine with 0.5 mg kg of ketamine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency rooms of Al-Zahra hospitals in Isfahan
Full name of responsible person
Dr. Azardokht Rahimi Nik
Street address
Hezar Jareeb St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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Shaghayegh Haghjoo
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Research Deputy, Isfahan University of Medical Sciences, Hezar Jarib street
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Azardokht Rahimi Nik
Position
Assisstant Professor
Latest degree
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Emergency Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan belongs to the government organization and it is not possible to share it

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available