

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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 ketamine at 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 lidocaine injection, only lidocaine 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 than 18 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

zareian@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**

Isfahan

**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**

radius 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 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.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3620 2020

##### Email

azinik11@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoo

##### Street address

Research Deputy, Isfahan University of Medical Sciences, Hezar Jarib street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 3070

##### Email

haghjoo@med.mui.ac.ir

##### 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

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

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## Person responsible for scientific inquiries

#### Contact

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Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Azardokht Rahimi Nik

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##### Latest degree

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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