

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### Comparison of the analgesic effect of lidocaine, pethidine and their composition in Bier Block anesthesia in patients with distal radius fracture

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the analgesic effect of lidocaine, pethidine and the combined of both in the Bierblock method in patients with distal radius fractures referred to the orthopedic operating room of Shahid Bahonar Hospital in Kerman in 2022.

##### Design

Clinical trial has 3 groups, with factorial groups (Control group: lidocaine (3mg/kg) Intervention group1: pethidine (0/6mg/kg) Intervention group2: both lidocaine (3mg/kg) and pethidine (0/6mg/kg) ), double-blind, randomized, phase 2 on 90 patients. Using random numbers a third party will assign them to three groups.

##### Settings and conduct

Location: Operating room of Bahonar Hospital in Kerman  
Double-blind. Before starting the patient's VAS will be measured. Drugs will be injected intravenously then a tourniquet will be placed on the arm of the operated hand. Cuff pressure will 150 mm Hg above systolic pressure, A minimum of 250 mm Hg will be adjusted. The disappearing of the radial pulse will confirm sufficient tourniquet pressure. Then the complications of CNS and heart and the amount of sensory and motor block will be evaluated. Due to the colorlessness of the drugs, the patient will be blind. Only the anesthesiologist will be aware of the type of medication, and therefore the assessing physician will be unaware of the analgesic treatment protocol.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: distal radius fracture and age between 18 to 65 years  
Exclusion criteria: Allergy to local anesthetics, heart, Kidney, Lung, Brain disease Diabetes, Allergy to pethidine and other drugs and Drug users

##### Intervention groups

Control group: lidocaine (3mg/kg) group1: pethidine (0/6mg/kg) group2: both lidocaine (3mg/kg) and pethidine (0/6mg/kg)

#### Main outcome variables

Pain sensation is assessed based on VAS. The degree of sensation of touch will be scored from zero to two (no sense: zero, vague sense: 1 and full sense: 2)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211224053507N1**

Registration date: **2022-01-28, 1400/11/08**

Registration timing: **prospective**

Last update: **2022-01-28, 1400/11/08**

Update count: **0**

##### Registration date

2022-01-28, 1400/11/08

##### Registrant information

##### Name

Mansour Mortezaazadeh Meimand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3223 9181

##### Email address

drm7039970399@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-02-04, 1400/11/15

##### Expected recruitment end date

2022-08-06, 1401/05/15

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the analgesic effect of lidocaine, pethidine and their composition in Bier Block anesthesia in patients with distal radius fracture

**Public title**  
Comparison of the effect of pethidine, lidocaine the combined of both on pain management in local anesthesia in wrist fractures

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Distal radius fracture Age between 18 and 65 years  
**Exclusion criteria:**  
Allergy to local anesthetics Uncontrolled heart disease  
Kidney diseases Lung diseases Brain diseases Diabetes  
Allergy to pethidine and other drugs Drug users  
Dissatisfaction with participation in the study

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, patients were randomly divided into 3 groups of 30 using a sequence of random numbers made by SAS statistical software. Based on this method, a random list of numbers is made and the assignment of patients to groups is determined based on the order of their entry. Sealed, opaque numbered envelopes were used to hide randomization

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
This study is performed in a double-blind manner. The drugs will be injected intravenously. Due to the colorlessness of the drugs, the patient will be blind. Only the anesthesiologist will be aware of the type of medication, and therefore the researcher and the assessing physician will be unaware of the analgesic treatment protocol.

**Placebo**  
Not used

**Assignment**  
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kerman university of medical science

##### Street address

Shahid Bamonar Hospital., Sepah St., Kerman

##### City

Kerman

##### Province

Kerman

##### Postal code

7613747181

#### Approval date

2021-11-24, 1400/09/03

#### Ethics committee reference number

IR.KMU.AH.REC.1400.203

## Health conditions studied

### 1

#### Description of health condition studied

Fracture of lower end of radius

#### ICD-10 code

S52.5

#### ICD-10 code description

Fracture of lower end of radius

## Primary outcomes

### 1

#### Description

The pain score in each group

#### Timepoint

Ten minute intervals until the end of the operation

#### Method of measurement

Numeric pain intensity scale (VAS Scoring system)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: receive lidocaine (3mg/kg)

#### Category

Treatment - Drugs

2

**Description**

Intervention group: receive pethidine (0/6mg/kg)

**Category**

Treatment - Drugs

3

**Description**

Intervention group: receive both lidocaine (3mg/kg) and pethidine (0/6mg/kg)

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shahid Bahonar Hospital of Kerman

**Full name of responsible person**

Jafar Salehi

**Street address**

Shahid Bahonar Hospital., Sepah St., Kerman

**City**

Kerman

**Province**

Kerman

**Postal code**

7613747181

**Phone**

+98 34 3223 5011

**Email**

DR.Jsalehi@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Abbas Pardakhti

**Street address**

Somayeh crossroad

**City**

Kerman

**Province**

Kerman

**Postal code**

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**Phone**

+98 34 3226 3815

**Email**

kmu\_research@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Mansour Mortezaazadeh Meimand

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Jafar salehi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Mansour Mortezaazadeh Meimand

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Postal code**

7613747181

**Phone**

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**Email**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

At the end of the study, some of the information, including the effect of prescribing her, pethidine, lidocaine and the combination of both on the bier block anesthesia on distal radius fractures surgery, it will share with health workers.

### When the data will become available and for how long

2 months after data analysis

### To whom data/document is available

Health researchers

### Under which criteria data/document could be used

In order to use the results and during the written request

### From where data/document is obtainable

Mansour Mortezaazadeh Meimand-Email

### What processes are involved for a request to access data/document

The purpose of accessing data - requesting e-mail-After a week

### Comments