

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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Somayeh crossroad

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Province

Kerman

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7619813159

Phone

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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

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Other areas of specialty/work

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Contact

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Full name of responsible person

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Position

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Latest degree

Medical doctor

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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