

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of femoral blockade of lidocaine and ketamine with lidocaine and dexamethasone on pain relief after femoral fracture surgery

Protocol summary

Study aim

Comparing the effects of lidocaine femoral block with lidocaine and ketamine with lidocaine and dexamethasone on pain reduction after hip fracture surgery. Using the results of the study in order to use a more appropriate drug in femoral block, reducing postoperative pain in patients, reducing the use of narcotic drugs to reduce postoperative pain.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. Computer generated random numbers were used for randomization.

Settings and conduct

In the operating rooms of Ahvaz Golestan Hospital, after hip fracture surgery, patients are divided into 3 groups before transfer to recovery and femoral block is performed for them.

Participants/Inclusion and exclusion criteria

Entry requirements: All people who have undergone hip fracture surgery and are between 18 and 75 years old; Conditions of non-entry: people with history of seizures, history of drug allergy, history of coagulation disorders, drug addiction

Intervention groups

After the end of the surgery and before the patient is transferred to the recovery room, he is placed under femoral block. The first group receives lidocaine and ketamine intravenously, the second group receives lidocaine and dexamethasone intravenously, and the third group or the control group only receives lidocaine intravenously.

Main outcome variables

Pain level based on VAS criteria, pain-free duration after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231113060039N1**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **prospective**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

Registration date

2023-12-30, 1402/10/09

Registrant information

Name

Mohammadreza Mozafari oregani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3391 3456

Email address

mozafari.mr@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-11, 1402/10/21

Expected recruitment end date

2024-02-11, 1402/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of femoral blockade of lidocaine and ketamine with lidocaine and dexamethasone on pain relief after femoral fracture surgery

Public title

" Effect of lidocaine and ketamine on pain relief after femoral fracture surgery" : " Effect of lidocaine and dexamethasone on pain relief after femoral fracture surgery"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All people who have undergone femoral fracture surgery

Exclusion criteria:

People under 18 years old People over 75 years old

People who have a history of drug allergy People who have addictions

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomly entered patients will be divided into 3 groups with a ratio of 1:1:1 using a table of random numbers generated by the computer. The distribution results will be sealed in an envelope and kept by the research director. On the day of the operation, the main researcher will hand over the envelope to the anesthesia assistant to prepare the test liquid (blocking drug). In fact, the patients and the anesthesia assistant will be blinded to the nature of the type of anesthetic.

Blinding (investigator's opinion)

Double blinded

Blinding description

The randomly entered patients will be divided into 3 groups with a ratio of 1:1:1 using a table of random numbers generated by the computer. The distribution results will be sealed in an envelope and kept by the research director. On the day of the operation, the main researcher will hand over the envelope to the anesthesia assistant to prepare the test liquid (blocking drug). In fact, the patients and the anesthesia assistant will be blinded to the nature of the type of anesthetic.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan Hospital, Ahvaz
Jundishapur University of Medical Sciences

Street address

Golestan, Farvardin Street, Golestan Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6155965138

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1402.056

Health conditions studied

1

Description of health condition studied

Comparison of the pain level of patients after hip fracture surgery

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

The amount of pain

Timepoint

0 minutes after the operation, 15 minutes after the operation, 30 minutes after the operation, 1 hour after the operation, 2 hours after the operation, 3 hours after the operation, 6 hours after the operation, 9 hours after the operation, 12 hours after Operation, 24 hours after the operation

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: lidocaine 1% (4mg/kg) and ketamine (50mg) are injected intravenously after the operation.

Category

Treatment - Other

2

Description

The second intervention group: lidocaine 1% (4mg/kg) and dexamethasone (8mg) are injected intravenously after the operation.

Category

Treatment - Other

3

Description

Control group: Lidocaine 1% (4mg/kg) is injected intravenously after the operation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating rooms of Golestan Hospital, Ahvaz

Full name of responsible person

Mozafari Oregani, Mohammadreza

Street address

No.57, 2nd Gharbi St , kianpars, Ahvaz Town

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Khouzestan

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6155811856

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syadthsyn0@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Vaziri,Mahshid

Street address

Schoole of Medicine, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

City

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Province

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mozafari oregani, Mohammadreza

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No57 , Phase1 , 2nd Gharbi St , Kianpars , Ahvaz

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammadreza Mozafari oregani

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammadreza Mozafari oregani

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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