

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Venous Infusion of Lidocaine and Intravenous Injection of Pethidine for the Management of Acute Pain Due to Femoral Fractures

Protocol summary

Study aim

Comparison of efficacy of intravenous infusion of lidocaine vs pethidine on numerical rating scale (NRS) of pain in femoral fractures

Design

It is a randomized double blinded clinical trial with two parallel group (lidocaine and pethidine groups). The study population is 72 patients. We used www.sealedenvelope.com for randomization.

Settings and conduct

Patients administered to 501, Khanevadeh, Golestan, and Besat hospitals will be included to the study according to the inclusion and exclusion criteria. All patients will be monitored for vital signs and oxygen saturation. 3 mg/kg of lidocaine is intravenously administered within 20 minutes for lidocaine group. Pethidine group will receive 25 mg of intravenous pethidine. We will use numerical rating scale (NRS) for pain measurement. The list of randomization blocks and treatment groups will be provided to anesthesiologist. General practitioner, emergency physician, patients, and statistician will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Age more than 18 years-old 2. Femoral bone fracture 3. Severe pain based on NRS ($\text{NRS} \geq 7$) Exclusion Criteria: 1. Age more than 70 years-old 2. Crush injury of limb and open fractures 3. Acute diseases except of fractures 4. Pregnancy 5. Presence or history of cardiac block or bradycardia 6. Presence or history of seizure 7. Neuromuscular diseases 8. Neuropathic disease 9. Diabetes 10. History of consumption of analgesic or anti-inflammatory drugs 11. History of opioids consumption 12. Allergic history of lidocaine and pethidine

Intervention groups

3 mg/kg of lidocaine is intravenously administered within 20 minutes for lidocaine group. Pethidine group will receive 25 mg of intravenous pethidine.

Main outcome variables

1. Pain severity (based on NRS) 60 minutes after drug administration 2. Incidence of adverse events in each treatment group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231213060355N1**

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

Mehrshad Namazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Venous Infusion of Lidocaine and Intravenous Injection of Pethidine for the Management of Acute Pain Due to Femoral Fractures

Public title
Analgesic Effect of Intravenous Lidocaine in Femoral Fractures

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥ 18 years-old Femoral bone fracture Severe pain based on numerical rating scale of pain (NRS) ($\text{NRS} \geq 7$)
Exclusion criteria:
Age > 70 years-old Crush injury of limb and open fractures Acute diseases except of fractures Pregnancy Presence or history of cardiac block or bradycardia Presence or history of seizure Neuromuscular diseases Neuropathic disease Diabetes History of consumption of analgesic or anti-inflammatory drugs History of opioids consumption Allergic history of lidocaine and pethidine

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization is used for randomization of participants. We will use www.sealedenvelope.com website for randomization and providing blocks. The block size is 4. The treatment groups will be "A" and "B".

Blinding (investigator's opinion)
Double blinded

Blinding description
The list of randomization blocks and treatment groups will be provided to anesthesiologist. Anesthesiologist will define the treatment groups A and B (lidocaine and pethidine). General practitioner, emergency physician, and statistician will not access to the list and they are blinded. Type of treatment groups and drugs (A and B) will not be provided to research contributors, except anesthesiologist. Before enrolment, written informed consent will be obtained from study participants. However, type of drugs will not be provided to patients. At the end of the study, statistician and general physician will analyze the data.

Placebo
Not used

Assignment
Parallel

Other design features
In this study, for the first time we will evaluate the efficacy of infusion of intravenous lidocaine (3 mg/kg/20 minutes) in patients with femoral bone fractures compared to intravenous pethidine (in emergency room). If the intravenous lidocaine shows

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of AJA University of Medical Sciences

Street address

AJA university of medical sciences, Etemad zadeh street, Fatemi-Gharbi Street, Tehran, Iran.

City

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Province

Tehran

Postal code

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Approval date

2023-11-27, 1402/09/06

Ethics committee reference number

IR.AJAUMS.REC.1402.168

Health conditions studied

1

Description of health condition studied

Femoral bone fracture

ICD-10 code

S72

ICD-10 code description

Fracture of femur

Primary outcomes

1

Description

Numerical Rating Scale of Pain

Timepoint

Before drug administration, 10, 20, 30, 40, 50, 60 minutes after drug administration

Method of measurement

Visual Analogue Scale (VAS) for Pain

Secondary outcomes

1

Description

Drug adverse events

Timepoint

During the 4 hours after drug administration

Method of measurement

Vital sign monitoring and evaluating the signs and symptoms

Intervention groups

1

Description

Intervention group: Intravenous infusion of lidocaine (3 mg/kg during 20 minutes, Maximum dose 200 mg)

Category

Treatment - Drugs

2

Description

Control group: Intravenous pethidine (25 mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Saeed Shiralizadeh Dini

Street address

Besat Hospital, Takhti crossroad, Hejrat street, Basij highway

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mehrshad Namazi

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Imam Reza Hospital, Etemadzadeh street, Dr Fatemi street

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3

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

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Golestan hospital, Sayyad Shirazi highway, Pasdaran crossroad, Tehran

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4

Recruitment center

Name of recruitment center

Khanevadeh Hospital

Full name of responsible person

Mehrshad Namazi

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Khanevadeh Hospital, Kaj street, Bahar Shiraz street, Shariati street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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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

Artesh 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**

Artesh University of Medical Sciences

Full name of responsible person

Mehrshad Namazi

Position

Assistant 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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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable