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 (NRS>=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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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) (NRS>=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 sizs 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

Tehran

Province

Tehran

Postal code

1411718541

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
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2

Recruitment center
Name of recruitment center
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Recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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