Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Studying the intravenous lidocaine infusion effect on pain in patients undergoing femoral neck fracture surgery

Protocol summary

Study aim
Studying the intravenous lidocaine infusion effect on pain in patients undergoing femoral neck fracture surgery

Design
A double-blind, randomized clinical trial study with parallel groups and phase 3 on 64 patients.Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct
This study will be conducted on patients who are candidates for femoral neck fracture surgery referring to Urmia Imam Khomeini hospital. The study will be conducted as a double-blind clinical trial. The patient and the researcher evaluating the outcomes will be blind to the allocation of patients into intervention or placebo groups.

Participants/Inclusion and exclusion criteria
In this study, 64 patients undergoing femoral neck fracture surgery with age between 18 to 85 years will be included. Patients with a history of cardiovascular, liver, and kidney diseases, endocrine diseases, and users of opioids, analgesics and steroids will be excluded.

Intervention groups
First, all patients will receive intravenous midazolam (0.05 mg/kg) and intravenous fentanyl (2 µg/kg) as premedication. 5 minutes later, propofol 2 mg/kg and atracurium 0.5 mg/kg will be injected. 10 minutes before the surgery, in the intervention group; firstly, 1.5 mg/kg intravenously of lidocaine solution 1% will be injected; then the infusion of lidocaine 1% with a dose of 2 mg/kg per hour will be started with a syringe pump infusion device. in the placebo group; Firstly, 1.5 ml/kg of normal saline solution will be used intravenously and then 2 mg/kg per hour as an infusion.

Main outcome variables
pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033992N12**
Registration date: **2022-11-29, 1401/09/08**
Registration timing: **prospective**

Last update: **2022-11-29, 1401/09/08**
Update count: **0**

Registration date
2022-11-29, 1401/09/08

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3222 2010
Email address
karami.t@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-04-20, 1402/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the intravenous lidocaine infusion effect on pain

in patients undergoing femoral neck fracture surgery

Public title
Studying the intravenous lidocaine infusion effect on pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing femoral neck fracture surgery Age between 18 to 85 years Patients with physical status one and two according to the criteria of the American Anesthesia Association (ASA I, II)
Exclusion criteria:
History of allergy to local anesthetics Use of opioids and analgesics Use of steroids Pregnancy A history of heart failure Having liver and kidney diseases Uncontrolled blood pressure Endocrine diseases Body mass index (BMI) above 40 kg/m2
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into intervention or placebo groups using the block randomization method based on generated numbers by Random allocation software. Thus, in this software, first, the number of groups and the total determined sample size will be entered, and then in the block section, the Block randomization method will be implemented. According to the total sample size (64 patients), 16 blocks of 4 will be used. Patients will be allocated to intervention or placebo groups based on generated numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted as a double-blind clinical trial. The patient and the researcher evaluating the outcomes will be blind to the allocation of patients into intervention or placebo groups. Syringes containing drug and placebo will be similar in shape and size and the drug will be prescribed by an anesthesiologist (other than the outcome assessor). so, the table of computer-generated numbers will be given to the anesthesiologist. The anesthesiologist will enter the patients into groups according to the order of numbers. Finally, the name of groups will be encoded with the letters A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2022-09-21, 1401/06/30
Ethics committee reference number
IR.UMSU.REC.1401.251

Health conditions studied

1

Description of health condition studied
Fracture of neck of femur
ICD-10 code
NC72.2
ICD-10 code description
Fracture of neck of femur

Primary outcomes

1

Description
Pain intensity
Timepoint
Recovery, 6, 12 and 24 hours after the intervention
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Administration of fentanyl as analgesic
Timepoint
During 24 hours after the intervention
Method of measurement
no, yes

2

Description
Systolic blood pressure
Timepoint
Before, recovery, 6, 12 and 24 hours after the intervention
Method of measurement
monotring

3

Description
diastolic blood pressure
Timepoint
Before, recovery, 6, 12 and 24 hours after the intervention
Method of measurement
monotring

Intervention groups

1

Description
Intervention group: First, all patients will receive intravenous midazolam (0.05 mg/kg) and intravenous fentanyl (2 µg/kg) as premedication. 5 minutes later, propofol 2 mg/kg and atracurium 0.5 mg/kg will be injected. 10 minutes before the surgery, in the intervention group; firstly, 1.5 mg/kg intravenously of lidocaine solution 1% will be injected; then the infusion of lidocaine 1% with a dose of 2 mg/kg per hour will be started with a syringe pump infusion device.
Category
Treatment - Drugs

2

Description
Control group: First, all patients will receive intravenous midazolam (0.05 mg/kg) and intravenous fentanyl (2 µg/kg) as premedication. 5 minutes later, propofol 2 mg/kg and atracurium 0.5 mg/kg will be injected. 10 minutes before the surgery, 1.5 ml/kg of normal saline solution will be used intravenously and then 2 mg/kg per hour as an infusion.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Imam Khomeini Hospital
Full name of responsible person
Dr. Tohid Karami
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Saber Gholizadeh
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Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Tohid Karami
Position
Assistant professor
Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.
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Person responsible for updating data

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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
Confidentiality of patient information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable