

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, Jihad 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.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Phone

+98 44 3345 7286

Email

karami.t@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

Street address

Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

gholizadeh.s@umsu.ac.ir

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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Province

West Azarbaijan

Postal code

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Phone

+98 44 3345 7286

Email

karami.t@umsu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Tohid Karami

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Phone

+98 44 3245 7286

Email

karami.t@umsu.ac.ir

Person responsible for updating data**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.

City

Urmia

Province

West Azarbaijan

Postal code

57571-89397

Phone

+98 44 3245 7286

Email

karami.t@umsu.ac.ir

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