Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparing of the analgesic effect of pericapsular ultrasound-guided nerve group block and fascia iliaca block in patients with hip fracture for neuraxial block; a pilot study

Protocol summary

Study aim
Comparing of the analgesic effect of pericapsular ultrasound-guided nerve group block and fascia iliaca block in patients with hip fracture for neuraxial block as a pilot study

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients

Settings and conduct
This double-blind clinical trial study will be performed on 50 patients between the ages of 18-80 years in two groups (pericapsular nerve block and fascia iliac with ultrasound block) in Imam Khomeini hospital in Urmia. Pain will be checked before, 10 minutes after block and before positioning for neuraxial anesthesia using visual analog scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with hip fracture, American Society of Anesthesiologists (ASA) I and II, Lack of deformity in spinal, Age between 18 to 80 years; Exclusion criteria: Having heart disease, Sensitivity to local anesthetics, Coagulopathy disorders

Intervention groups
Intervention group 1: Pericapsular ultrasound-guided nerve block Intervention group 2: Fascia iliaca block

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033992N8**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **registered_while_recruiting**
Last update: **2021-08-29, 1400/06/07**
Update count: **0**

Registration date
2021-08-29, 1400/06/07

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

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-21, 1400/05/30

Expected recruitment end date
2022-01-20, 1400/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing of the analgesic effect of pericapsular ultrasound-guided nerve group block and fascia iliaca block in patients with hip fracture for neuraxial block; a pilot study

Public title
Analgesic effect of pericapsular nerve and fascia iliaca block in hip fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Lack of deformity in spinal American Society of Anesthesiologists (ASA) I and II Age between 18 to 80 years

Exclusion criteria:

Having heart disease Sensitivity to local anesthetics Coagulopathy disorders

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

40 patients, using random allocation software, were randomly divided into pericapsular nerve block and fascia iliaca block groups. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers. The tool used is random allocation software version 2.0 in which by selecting the number of groups and the sample size, a random sequence sheet is provided for the control and intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and statistical analyzers were unaware of the patient was anesthetized using pericapsular nerve block and fascia iliaca block. Anesthesia was performed by an anesthesiologist in the operating room for randomly selected patients. In this way, the patient was only aware that the block was performed on him/her, but was unaware of its type, and also the statistical analyzer will receive the data in code A and B for the two intervention groups.

Placebo

Not 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

No30., Jahad Sq., Resalat St., Urmia University of Medical Sciences, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5715833631

Approval date

2021-07-14, 1400/04/23

Ethics committee reference number

IR.UMSU.REC.1400.160

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

Pain will be checked before, 10 minutes after block and before positioning for neuraxial anesthesia using visual analog scale

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the precapsular block, 20 ml of bupivacaine 0.25% (produced by Tebshahr company) using an ultrasound guide for analgesia is injected deep into the plate between the muscle and the fascia, in front of which is the pseudos tendon and behind which is the pubic bone ramus, and the patient is in a supine position.

Category

Treatment - Drugs

2

Description
Intervention group 2: In the fascia iliac block, 20 ml of 0.25% (produced by Tebshahr company) bupivacaine using an ultrasound guide for analgesia is injected deep into the fascia iliac and in the upper lateral part of the iliac muscle, and the patient is in a supine position.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Tohid Karami
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Tohid Karami
Position
Assistant professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Reporting of results as a published article
When the data will become available and for how long
After publishing of article
To whom data/document is available
Researchers
Under which criteria data/document could be used
As published article
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
If necessary access to the data can be done through the e-mail address of the corresponding author that will be written in the published article.
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