

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

###### Email address

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., Jihad 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

##### Street address

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

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##### Email

karami.tohid@gmail.com

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Iraj Mohebbi

##### Street address

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

##### City

Uremia

##### Province

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##### Phone

+98 44 3193 7224

##### Email

mohebbi\_iraj@yahoo.co.uk

##### 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

Tohid Karami

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

#### Contact

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##### Position

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##### Other areas of specialty/work

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**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Tohid Karami

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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.

**Comments**