# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigating the effect of using dexmedetomidine in fascia iliaca block on postoperative analgesia in patients undergoing femoral fractures surgery

## Protocol summary

**Study aim**
Investigating the effect of using dexmedetomidine in fascia iliaca block on postoperative analgesia in patients undergoing femoral fractures surgery

**Design**
Clinical trial with double-blinded parallel groups randomized using Random Allocation Software (RAS) (in 20 blocks of 4)

**Settings and conduct**
In this double-blind study, patients between the ages of 25 and 75 years who are candidates for femoral fracture surgery under spinal anesthesia in Urmia Imam Khomeini Hospital will be included. the patients and the researcher will be blinded about the intervention or control groups.

**Participants/Inclusion and exclusion criteria**
In current study, 75 patients with femoral fracture surgery under spinal anesthesia , American Society of Anesthesiologists (ASA) I and II and age between 25 to 75 years will include. the exclusion criteria including any contraindication for spinal anesthesia, obesity (body mass index more than 35 kg/m2), Local infection at the injection site in the groin, previous surgery at the injection site, Injecting drug addicts, receiving any type of analgesic two hours before surgery, mental and psychological disorders, multi-trauma fractures, a history of severe heart disease, a history of kidney and respiratory diseases, Liver disease, pregnancy and hematologic disorders.

**Intervention groups**
Fascia iliac block will be performed in the intervention group using 20 cc of bupivacaine 0.25 with 0.5 cc of dexmedetomidine 50µg and in the control group using only 20 cc of bupivacaine 0.25.

**Main outcome variables**
Duration of analgesia

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170515033986N4**
Registration date: **2022-03-24, 1401/01/04**
Registration timing: **prospective**

Last update: **2022-03-24, 1401/01/04**
Update count: **0**

**Registration date**
2022-03-24, 1401/01/04

**Registrant information**

**Name**
Nazli Karami

**Name of organization / entity**
Urmia University of Medical Siences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 44 3346 9932

**Email address**
karami.n@umsu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-04-05, 1401/01/16

**Expected recruitment end date**
2022-07-22, 1401/04/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
Investigating the effect of using dexmedetomidine in fascia iliaca block on postoperative analgesia in patients undergoing femoral fractures surgery

**Public title**
The effect of dexmedetomidine on postoperative analgesia in patients undergoing femoral fracture surgery

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients with femoral fracture surgery under spinal anesthesia Patients with ASA I and ASA II Age between 25 to 75 years

**Exclusion criteria:**
Any contraindication for spinal anesthesia Obesity (body mass index more than 35 kg/m2) Local infection at the injection site in the groin Previous surgery at the injection site Injecting drug addicts Receiving any type of analgesic two hours before surgery Mental and psychological disorders Multi-trauma fractures A History of severe heart disease A history of kidney and respiratory diseases Liver disease Pregnancy Hematologic disorders

**Age**
From **25 years** old to **75 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients will be divided into intervention and control groups using permuted block randomization based on generated numbers by random allocation software (20 blocks of 4 letters).

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Current study is a double blind study. The patient and the person who will be assessed the outcomes (anesthesia assistant) will be blind about the intervention or control groups. therefore, the drugs will be drawn and coded inside the syringes by an anesthesiologist, and the block will be performed by an anesthesia assistant that who is unaware of the contents of the syringes.

**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**
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.

**City**
Urmia

**Province**
West Azarbaijan

**Postal code**
5714783734

**Approval date**
2021-10-30, 1400/08/08

**Ethics committee reference number**
IR.UMSU.REC.1400.268

## Health conditions studied

### 1

**Description of health condition studied**
Analgesia in femoral fractures

**ICD-10 code**
G89.1

**ICD-10 code description**
Acute pain, not elsewhere classified

## Primary outcomes

### 1

**Description**
Duration of analgesia

**Timepoint**
The duration of analgesia until the onset of pain felt by the patient in 24 hours after surgery

**Method of measurement**
timing

### 2

**Description**
Prescribing an analgesic

**Timepoint**
Prescribing an analgesia in recovery, 2, 6, 12 and 24 hours after surgery

**Method of measurement**
Patient request

## Secondary outcomes

### 1

**Description**
Time to Prescription an analgesic
**Timepoint**
24 hours after surgery
**Method of measurement**
Timing

### 2

**Description**
Pain severity
**Timepoint**
In recovery, 2, 6, 12 and 24 hours after surgery
**Method of measurement**
Visual Analog Scale (VAS)

### 3

**Description**
Complications of Iliaca fascia block
**Timepoint**
In recovery, 2, 6, 12 and 24 hours after surgery
**Method of measurement**
Clinical examination

## Intervention groups

### 1

**Description**
Intervention group: Iliaca fascia block will beperformed using 20 cc of bupivacaine 0.25% with 0.5 cc of dexmedetomidine 50µg.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Iliaca fascia block will be performed using only 20 cc of bupivacaine 0.25%.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Urmia Imam Khomeini hospital
**Full name of responsible person**
Dr. Nazli Karami
**Street address**
Imam Khomeini hospital, Ershad street, Modarres Blvd., Urmia, Iran.
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
57157-81351
**Phone**
+98 44 3198 8293
**Email**
karami.n@umsu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
Dr. Iraj Mohebbi
**Street address**
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
5714783734
**Phone**
+98 44 3222 2010
**Email**
mohebbi.i@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. Nazli Karami
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**

Anesthesiology
**Street address**
Imam Khomeini hospital, Ershad street, Modarres blvd., Urmia, Iran.
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
57157-81351
**Phone**
+98 44 3198 8293
**Email**
karami.n@umsu.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
Dr. Nazli Karami
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Imam khomeini hospital, Ershad street, Modarres Blvd., Urmia, Iran.
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
57157-81351
**Phone**
+98 44 3198 8293
**Email**
karami.n@umsu.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
Dr. Nazli Karami
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Imam Khomeini hospital, Ershad street, Modarres Blvd., Urmia, Iran.
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
57157-81351
**Phone**
+98 44 3198 8293
**Email**
karami.n@umsu.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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**
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**
No - There is not a plan to make this available
**Title and more details about the data/document**
The results of the study will be available as an article. Other files, including data and the consent form, can also be accessed through email address of corresponding author.
**When the data will become available and for how long**
after published article
**To whom data/document is available**
researchers
**Under which criteria data/document could be used**
The data can be provided for use in meta-analysis, network meta-analysis or any secondary analysis with research purposes.
**From where data/document is obtainable**
corresponding author (Nazli Karami). Data will be available by sending an email to karami.n@umsu.ac.ir
**What processes are involved for a request to access data/document**
By email address to karami.n@umsu.ac.ir
**Comments**