

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Sciences

Country

Iran (Islamic Republic of)

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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	Other design features
Scientific title Investigating the effect of using dexmedetomidine in fascia iliaca block on postoperative analgesia in patients undergoing femoral fractures surgery	Secondary Ids empty
Public title The effect of dexmedetomidine on postoperative analgesia in patients undergoing femoral fracture surgery	Ethics committees
Purpose Treatment	1
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	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
Age From 25 years old to 75 years old	Health conditions studied
Gender Both	1
Phase 3	Description of health condition studied Analgesia in femoral fractures ICD-10 code G89.1 ICD-10 code description Acute pain, not elsewhere classified
Groups that have been masked • Participant • Investigator • Outcome assessor	Primary outcomes
Sample size Target sample size: 80	1
Randomization (investigator's opinion) Randomized	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
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).	2
Blinding (investigator's opinion) Double blinded	Description Prescribing an analgesic Timepoint Prescribing an analgesia in recovery, 2, 6, 12 and 24 hours after surgery Method of measurement Patient request
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	

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 be performed 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

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Province

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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, Jihad 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. Nazli Karami

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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