Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 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)

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+98 44 3346 9932

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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

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.
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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.
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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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Imam Khomeini hospital, Ershad street, Modarres blvd., Urmia, Iran.
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Person responsible for updating data

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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