Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Ultrasound guided femoral nerve vs. fascia iliaca block: A randomized trial of analgesia in femoral injury

Protocol summary

Study aim
To compare the analgesic effects of ultrasound guided femoral nerve block with ultrasound guided fascia iliaca block in femoral fractures

Design
Randomized, parallel group trial with blinded outcome assessment. Randomization will be done by simple randomization using random numbers table.

Settings and conduct
This study will be conducted in Bahonar Academic Hospital, a level 2 urban trauma center located in Kerman, Iran. Enrolled patients will undergo ultrasound guided fascia iliaca or femoral nerve block, performed by a specifically trained senior resident of emergency medicine, which will be directly supervised by an attending physician of emergency medicine with 2 years of academic experience in both of the block methods. Assessment of pain scores (using a numeric rating scale) will be performed before and 20 minutes and 1 hour after the procedure and in the time of disposition from the emergency department by a registered nurse on duty who is blinded to the method of block.

Participants/Inclusion and exclusion criteria
All patients over 18 years of age with femoral fractures will be included. Those with distracting injuries, impaired consciousness, lidocaine hypersensitivity, coagulopathy, sensory deficit and those who have already received pain medications will be excluded.

Intervention groups
The two groups will undergo two kinds of ultrasound guided blocks: for group 1 fasica iliaca block and for group 2 femoral nerve block will be performed.

Main outcome variables
Pain scores 20 minutes and 1 hour after the procedure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131226015941N8**
Registration date: **2019-05-16, 1398/02/26**
Registration timing: **prospective**

Last update: **2019-05-16, 1398/02/26**
Update count: **0**

Registration date
2019-05-16, 1398/02/26

Registrant information

Name
Amirhossein Mirafzal

Name of organization / entity
Kerman University of Medical sceinces

Country
Iran (Islamic Republic of)

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+98 34 1247 4638

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Ultrasound guided femoral nerve vs. fascia iliaca block: A randomized trial of analgesia in femoral injury

Public title
Ultrasound guided femoral nerve vs. facia iliaca block
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age Patients with proximal femoral fracture Patients with femoral shaft fracture
Exclusion criteria:
Presence of distracting injury Impaired consciousness Hypersensitivity to lidocaine Coagulopathy Sensory deficit in the limbs for any reason Not willing to participate in the study Receiving pain killers before enrollment
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized by simple randomization method using random numbers table. Each patient will be the unit of randomization. The sequence of numbers will be read from top to bottom, starting from the left column. Even numbers will be assigned as group 1 (fascia iliaca block) and odd numbers as group 2 (femoral nerve block). Allocation concealment will be done using sealed opaque envelopes. The group assigned to each number will be written on a small paper and put in the envelope. The sequential numbers of the patients will be written on the envelopes, which are kept safe by the head-nurse of the emergency department.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants of the study will be blinded to the study group since the syringes and agents used for both blocks are similar (lidocaine) and the techniques of block are almost the same from the outside view (the main difference between the two methods is recognizable by the ultrasound view which will not be available for the patient). The person who will be evaluating the pain scores of the patient before and after the blocks will be blinded to the procedure. He/She will be a registered nurse on duty.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Kerman University of Medical Sciences
Street address
Somaye crossroad, Jahad Blv., Ebne-Sina St., next to Besat Clinic
City
Kerman
Province
Kerman
Postal code
7610813159
Approval date
2019-04-23, 1398/02/03
Ethics committee reference number
IR.KMU.REC.1398.050

Health conditions studied

1

Description of health condition studied
Femoral fracture
ICD-10 code
S72
ICD-10 code description
Unspecified fracture of femur

Primary outcomes

1

Description
Pain score by numeric rating scale at 20 minutes after the procedure
Timepoint
Twenty minutes after the procedure
Method of measurement
Asking the patient

2

Description
Pain score by numeric rating scale at 1 hour after the procedure
Timepoint
One hour after the procedure
Method of measurement
Asking the patient

Secondary outcomes

1

Description
Total administered dose of intravenous fentanyl (if administered)
Timepoint
After 1 hour from the procedure to the time of disposition
Method of measurement
Recording by the investigator

2

Description
Complications of the procedure
Timepoint
From the beginning of the procedure to the discharge of the patients
Method of measurement
Evaluation by the investigator

Intervention groups

1

Description
Intervention group: Fascia iliaca block will be performed under the real time vision by the ultrasound device (Mindray, 2012, China) and after proper sterile preparations. The block will be performed by a senior resident of Emergency Medicine trained by a pain medicine fellow. The procedure will be supervised by an attending physician of emergency medicine with certification of ultrasound guided nerve blocks and 2 years experience of the procedure. Firstly, fascia iliaca will be recognized in the ultrasound view of the lowest part of the abdomen and using a 20 gauge needle, 20 ml of 1% lidocaine (Caspiantamin, Iran) will be injected under the fascia; tissue expansion is checked by ultrasound in the time of injection.
Category
Treatment - Drugs

2

Description
Control group: Femoral nerve block is assigned as the control procedure since there have been more research on it and its superiority relative to systemic analgesia has been confirmed by the literature. Femoral nerve block will be performed under the real time vision by the ultrasound device (Mindray, 2012, China) and after proper sterile preparations. The block will be performed by a senior resident of Emergency Medicine trained by a pain medicine fellow. The procedure will be supervised by an attending physician of emergency medicine with certification of ultrasound guided nerve blocks and 2 years experience of the procedure. Firstly, femoral nerve, artery and vein will be recognized in the ultrasound view of the inguinal region and using a 20 gauge needle, 20 ml of 1% lidocaine (Caspiantamin, Iran) will be injected in the sheath covering the nerve (puncture of the nerve itself should be avoided by the performer); tissue expansion is checked by ultrasound in the time of injection.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Academic Hospital
Full name of responsible person
Amirhossein Mirafzal
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Gharani St.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty
Street address
Somaye crossrd., Jahad blv., Kerman
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7116913555
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+98 34 3226 3855
Email
abpardakhty@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

All deidentidied data set will be available for primary and secondary outcomes.

When the data will become available and for how long

Starting 1 year after publication

To whom data/document is available

The data will be available only for people in academic positions.

Under which criteria data/document could be used

No limitation considered for this part.

From where data/document is obtainable

please email your request to mirafzal@kmu.ac.ir The responsible person is Amirhossein Mirafzal

What processes are involved for a request to access data/document

The data set will be provided in one month

Comments