

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Ultrasound-Guided Femoral Nerve Block and Intravenous Fentanyl in Pain Management of the Patients with Hip Fracture: A Comparative Study

Protocol summary

Study aim

The purpose of this study was to evaluate and compare ultrasound-guided femoral nerve block and intravenous fentanyl administration in relieving the pain of the patient with hip fracture.

Design

This study was a clinical trial study with a control group, with parallel groups of one-way blind, randomized, phase 3 on 58 patients. Random number tables are also used for randomization.

Settings and conduct

This study is a clinical trial study that will be performed on 40 patients with unilateral isolated proximal femur fracture complaints referred to Shahid Bamonar Hospital in Kerman.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with unilateral isolated proximal femur fracture complaints and American Society of Anesthesiologists (ASA) score I and II.
Exclusion criteria: Subjects with allergy to amide local anesthetics, peripheral neuropathy, analgesic taking 8 hours before surgery, previous block at the affected site, mental disorders, risk of hemorrhage, drug addiction, other concomitant fractures and a history of fracture at the same site, diabetics and patients who did not mention having pain

Intervention groups

The patients were divided into two groups using random number tables. The first group was evaluated for The National Reporting System for Adult Education (NRS) criteria (0 to 10) half an hour before fentanyl injection and then received intravenous fentanyl at a dose of 1.5 µg / kg. After the injection, the patient's pain status was assessed at 15-minute intervals. The second group (FNB) was also evaluated by NRS approach followed by injection of 20 ml of 2-percent lidocaine solution guided by ultrasonography.

Main outcome variables

the pain of the patient with hip fracture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171009036661N4**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **retrospective**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3335 6220

Email address

m.mayel@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-07-11, 1394/04/20

Expected recruitment end date

2015-07-31, 1394/05/09

Actual recruitment start date

2015-09-21, 1394/06/30

Actual recruitment end date

2015-12-20, 1394/09/29

Trial completion date

2015-12-31, 1394/10/10

Scientific title

Ultrasound-Guided Femoral Nerve Block and Intravenous

Public title

Management of the Patients with Hip Fracture: A Comparative Study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with unilateral isolated proximal femur fracture complaints American Society of Anesthesiologists (ASA) score I and II

Exclusion criteria:

allergy to amide local anesthetics peripheral neuropathy analgesic taking 8 hours before surgery previous block at the affected site mental disorders risk of hemorrhage drug addiction other concomitant fractures and a history of fracture at the same site diabetics patients who did not mention having pain

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study patients randomly divided to intervention and control groups using random allocation sequence with SAS statistical software. according to this method, a simple randomization list product and patients` involvement in each group determine base on their order entry in emergency ward. we used Sequentially numbered, sealed, opaque envelopes for allocation concealment. patients (individuals) were the randomization units.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, main investigator and outcome assessor were blinded due to the sedation procedure and sonography was performed in isolated room. The data analyser were also blinded because all checklist was without name and contained only a code.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Vice chancellor research, Jahad blvd., Ebn-e sina st.,

City

Kerman

Province

Kerman

Postal code

7613747181

Approval date

2015-08-07, 1394/05/16

Ethics committee reference number

IR.KMU.REC.1394.373

Health conditions studied

1

Description of health condition studied

Acute pain due to unilateral isolated proximal femur fracture complaints

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

the pain of the patient with hip fracture

Timepoint

0, 15, 30, 45 and 60 minutes after intervention

Method of measurement

Numerical rating scale for pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who were evaluated for The National Reporting System for Adult Education (NRS) criteria (0 to 10) half an hour before fentanyl injection and then received intravenous fentanyl at a dose of 1.5 µg / kg. After the injection, the patient's pain status was

assessed at 15-minute intervals

Category

Treatment - Other

2

Description

Control group: Patients were also evaluated by NRS approach followed by injection of 20 ml of 2-percent lidocaine solution guided by ultrasonography

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid bahonar hospital

Full name of responsible person

Masoud Mayel

Street address

Shahid Bahonar Hospital, Qarani St.

City

Kerman

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7613747181

Phone

+98 34 3223 5011

Email

masoud.mayel@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhty

Street address

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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

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

Dr. Massoud mayel

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Massoud mayel

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available