Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between effect of bupivacaine 0.2% and 0.3% in ultrasound guided fascia iliaca plane block for analgesia after hip or femur surgery

Protocol summary

Summary

Each year, a large number of orthopedic surgeries is due to femur and pelvic fractures. Because of the complex nature of these fractures, post-operative care is very important. We conducted a double blind Randomized Clinical Trial to study the effect of effect of bupivacaine 0.2% and 0.3% for analgesia after hip or femur surgery. The study population consist of 40 candidate for femur and pelvic surgery in Rasul akram and Firouzgar hospitals. Patients with disorders such as peripheral neuropathy, drug addiction and multiple trauma will have been excluded. Participants will be assigned to 2 groups(A and B) using block randomization. In each group alternatively, anesthetic drug be injected and injection site will be checked. Participants and anesthesiologist will not be aware of the nature of the drug(The study is double blind). In order to pain relief, acetaminophen injection will be used every 6 hours for all Patients after operation. Sedation score using Ramsy scale at 2, 6, 12, 24 and 48 hours after operation and pain Severity using Visual Analog Scale(VAS) will be assessed. furthermore,vomiting, changes in blood pressure and heart rate within 48 hours after operation will be recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081014199N5**
Registration date: **2015-01-02, 1393/10/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-02, 1393/10/12

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between effect of bupivacaine 0.2% and 0.3% in ultrasound guided fascia iliaca plane block for analgesia after hip or femur surgery

Public title

Effect of bupivacaine for analgesia after hip or femur surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Any type of femur fracture, Any type of hip fracture, Individuals of all ages,Male and female, ASA

eligibility criteria(ASA>=1), Informed consent. Exclusion criteria: Peripheral neuropathy, drug addiction, mental disorders, Allergic reactions to amide anesthetic drugs, Concurrent multiple fractures in different organs(Multiple Trauma)

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences Central Campus, Shahid Hemmat Highway, Adjacent to Milad Tower, Tehran, Iran

City

Tehran

Postal code

Approval date

2013-09-13, 1392/06/22

Ethics committee reference number

130-243-92-د

Health conditions studied

1

Description of health condition studied

Postoperative pain

ICD-10 code

G89.18

ICD-10 code description

Pain during the period after surgery

Primary outcomes

1

Description

Postoperative pain

Timepoint

Pain score and sedation score were evaluated 2, 6, 12, 24 and 48 hours after operation(5 times)

Method of measurement

Two types of questionnaire: 1.Sedation score and 2. Visual Analog Scale

Secondary outcomes

1

Description

Heart rate

Timepoint

At 2, 6, 12, 24 and 48 hours after operation(5 times)

Method of measurement

Questionnaire (the number of heartbeats per minute)

2

Description

Patient satisfaction

Timepoint

Within 48 hours after operation(1 time)

Method of measurement

Questionnaire with likert scale (Low, moderate, good, excellent)

3

Description

Blood pressure

Timepoint

At 2, 6, 12, 24 and 48 hours after operation(5 times)

Method of measurement

Questionnaire (Mean of arterial blood pressure(With pressure gauge))

4

Description

Vomiting

Timepoint

At 2, 6, 12, 24 and 48 hours after operation(5 times)

Method of measurement

Questionnaire (Observation)

5

Description

Nausea

Timepoint

At 2, 6, 12, 24 and 48 hours after operation(5 times)

Method of measurement

Questionnaire (Self-declaration)

Intervention groups

1

Description
In group1: Injection Bupivacaine 0.2% (Manufacturer: Italy, Milan) in ultrasound guided fascia iliaca plane block
Category
Treatment - Drugs

2

Description
In group 2: Injection bupivacaine 0.3% (Manufacturer: Italy, Milan) in ultrasound guided fascia iliaca plane block
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital, Firouzgar Hospital
Full name of responsible person
Dr, poupak Rahimzadeh
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Rasoul Akram Hospital, Niyaesh Ave, Tehran,Iran. Firouzgar Hospital, Firouzgar Allay, Valadi ST, Behafarin ST, Karimkhan AVE, Vali-asr Sq, Tehran, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
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City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty