

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Name

Leila Mounesan

Name of organization / entity

Tehran University of Medical Sciences

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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

130-243-92-3

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

Street address

Rasoul Akram Hospital, Niyaesh Ave, Tehran,Iran.
Firouzgar Hospital, Firouzgar Allay, Valadi ST,
Behafarin ST, Karimkhan AVE, Vali-asr Sq, Tehran,
Iran

City

Tehran

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

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

Contact

Name of organization / entity

Rasoul Akram Hospital

Full name of responsible person

Dr. Poupak Rahimzadeh

Position

Anesthesiologist. Assistant professor

Other areas of specialty/work

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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