

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of fractionated dose of Bupivacaine and Fentanyl versus bolus dose injection in spinal anesthesia in lower limb fracture surgeries

Protocol summary

Study aim

Comparison of fractionated dose of Bupivacaine and Fentanyl versus bolus dose injection in spinal anesthesia in lower limb fracture surgery

Design

The present study will be conducted in a prospective single blind randomized controlled trial. This study will be performed on 60 patients aged 18-50 years with the American Society of Anesthesiologists (Physical Status) (ASA) 1-2, who were under the fractures of the lower limb surgery in Rasoul-e-Akram Hospital in 2016- 2017. Patients will be randomly divided into two groups using the closed envelopes they choose: Group A and Group B.

Settings and conduct

The present study will be conducted in Rasoul-e-Akram Hospital. Patients undergoing surgery for fracture of the lower limbs are randomly divided into two groups A and B. The spinal cord will be conducted at a sitting position at L3-L4 or L4-L5 levels using 23 gauge needles. Group A, will receive Fentanyl plus Bupivacaine, and patients position change to supine after 45 seconds. Group B, will receive half a dose of the drug (Fentanyl plus Bupivacaine) initially, and after another 45 seconds, half the other drug will be injected. In this study, the patient and person who performs spinal anesthesia are not blind to the study, and the researcher is the only person who is blind to the study and is not present in the room at the time of injection.

Participants/Inclusion and exclusion criteria

This prospective study is conducted on 60 patients with a range of 18-50 years old with ASA 1-2 which will undergo lower limb fractures surgeries in Rasoul-e-Akram Hospital in Tehran during 2016-2017. Patients with absolute spinal anesthesia contraindications such as refusal of the patient, localized sepsis, allergic to the anesthetic drugs, and the patient's inability to maintain position during the procedure, and to increase the ICP and spinal relative contraindications, patients with a BMI greater than 35 and deformities of the spine. Similarly, patients who did

not succeed in spinal anesthesia or who have a longer surgical duration than their spinal anesthesia have undergone general anesthesia and are excluded.

Intervention groups

Group A, a bolus dose, receives 25 micrograms Fentanyl plus 15 milligrams of Bupivacaine 0.5%, and patients position change to supine after 45 seconds. Group B, half a dose of the drug (25 µg Fentanyl plus 15mg of Bupivacaine 0.5%) is initially injected, and after another 45 seconds, half the other drug will be injected.

Main outcome variables

Onset of sensory block, Onset of motor block, Highest level of sensory block, Duration of sensory block, Duration of motor block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180121038462N1**

Registration date: **2018-03-11, 1396/12/20**

Registration timing: **retrospective**

Last update: **2018-03-11, 1396/12/20**

Update count: **0**

Registration date

2018-03-11, 1396/12/20

Registrant information

Name

Ghazaleh Khaef

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

khaef.gh@iums.ac.ir

Recruitment status

Recruitment complete**Funding source****Expected recruitment start date**

2016-04-08, 1395/01/20

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

2016-04-08, 1395/01/20

Actual recruitment end date

2017-08-23, 1396/06/01

Trial completion date

empty

Scientific title

Comparison of fractionated dose of Bupivacaine and Fentanyl versus bolus dose injection in spinal anesthesia in lower limb fracture surgeries

Public title

Comparison of two methods of Bupivacaine and Fentanyl injection in lower limb fracture surgeries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing surgery for lower limb fractures Age 18 to 50 years old ASA 1 to 2

Exclusion criteria:

Patients with absolute spinal anesthesia contraindication
Refusal of the patient Localized sepsis Allergy to the anesthetic drugs Patient's inability to maintain position during the procedure Increase ICP Spinal relative contraindications such as myelopathy or peripheral neuropathy Spinal stenosis history of spinal surgery Multiple sclerosis Spina bifida Aortic thrombosis Hypovolemia Hereditary coagulopathies Thromboprophylaxis (ambulatory lung) Systemic infections Patients with a BMI greater than 35 Spinal deformities Patients who did not succeed in spinal anesthesia Patients whose length of operation is longer than their spinal anesthesia length

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two groups of intervention and control by choosing one of the envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patients and person who performs spinal injections are not blind to the blind study, and only researcher is blind to the study. In this way, the researcher is not present in the room at the time of injection of anesthetic drug.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Iran University of Medical Science

Street address

Hemat Highway next to Milad Tower, Iran University of Medical Sciences, Faculty of Medicine

City

Tehran

Province

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.IUMS.FMD.REC1396.9511174026

Health conditions studied**1****Description of health condition studied**

Lower limb fracture surgery

ICD-10 code

s70-s79

ICD-10 code description

Injuries to the hip and thigh

2**Description of health condition studied**

Lower limb fracture surgery

ICD-10 code

S80-S89

ICD-10 code description

Injuries to the knee and lower leg

3**Description of health condition studied**

Lower limb fracture surgery

ICD-10 code

S90-S99
ICD-10 code description
Injuries to the ankle and foot

Primary outcomes

1

Description
Blood pressure
Timepoint
24 hours after surgery
Method of measurement
Noninvasive Blood Pressure Amplifier (NIBP)

2

Description
Heart rate
Timepoint
24 hours after surgery
Method of measurement
Electrocardiography

3

Description
Pruritus
Timepoint
24 hours after surgery
Method of measurement
Observation

4

Description
Urinary retention
Timepoint
24 hours after surgery
Method of measurement
Observation

5

Description
Shivering
Timepoint
24 hours after surgery
Method of measurement
Observation

6

Description
Respiratory distress
Timepoint
24 hours after surgery
Method of measurement
Clinical feature

7

Description

Nausea
Timepoint
24 hours after surgery
Method of measurement
Observation

8

Description
Vomiting
Timepoint
24 hours after surgery
Method of measurement
Observation

9

Description
Onset of sensory block
Timepoint
After the injection of anesthetic drug
Method of measurement
Pinprick test

10

Description
Onset of motor block
Timepoint
After the injection of anesthetic drug
Method of measurement
Modified bromage scale

11

Description
Highest level of sensory block
Timepoint
After the injection of anesthetic drug
Method of measurement
Pinprick test

12

Description
Duration of sensory block
Timepoint
After the injection of anesthetic drug
Method of measurement
Modified bromage scale

13

Description
Duration of motor block
Timepoint
After the injection of anesthetic drug
Method of measurement
Pinprick test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in intervention group, will receive half dose of 15 milligram of Bupivacaine 0.5 % and 25 micro gram of Fentanyl at first, and after 45 seconds half the other drug will be injected.

Category

Treatment - Drugs

2

Description

Control group: Patients in control group, will receive bolus dose of 15 milligram of Bupivacaine 0.5 % and 25 micro gram of Fentanyl and then will be placed in supine position after 45 seconds.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Qazale Khaef

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Rasoul Akram Hospital, Sattarkhan Ave., Nayesh Ave.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Qazale Khaef

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I have not yet decided on this.

When the data will become available and for how long

I have not yet decided on this.

To whom data/document is available

I have not yet decided on this.

Under which criteria data/document could be used

I have not yet decided on this.

From where data/document is obtainable

I have not yet decided on this.

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

I have not yet decided on this.

Comments