Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Thromboprofylaxis (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
Tehran

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
Observatioon

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., Mansouri Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Kazem Malakouti
Street address
Faculty of Medicine, Iran University of Medical Sciences, Hemat Highway next to Milad Tower
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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
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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