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
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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 Hypovolemic Hereditary coagulopathies Thromboprofylaxis (ambulatory lung) Systemic infections Patients with a BMI greater than 35 Spinal deformities Patients who did not succeed in spinal anesthesia

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
empty

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
empty

Secondary Ids
empty

Ethics committees
1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Iran University of Medical Science

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

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Province
Tehran

Postal code
143951370

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
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
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1

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khaef.gh@iums.ac.ir

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