Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial for comparison of effect of small dose of bupivacaine and sufentanil and normal dose of bupivacaine on hemodynamic variables in patients that underwent lower limb orthopedic surgery

Protocol summary

Summary

Objectives: Clinical trial for comparison of effect of small dose of bupivacaine and sufentanil and normal dose of bupivacaine on hemodynamic variables in patients that will underwent lower limb orthopedic surgery. Design: all of patients that will candidate for lower limb orthopedic surgery randomly will divide to two groups, one group that will undergo spinal block with low dose of bupivacaine and sufentanil and another group that will undergo spinal block with normal dose of bupivacaine. The hemodaynamic, sensory and motor block variables will compare between two groups. Setting and conduct: 150 patients will identify in this clinical trial study for lower limb orthopedic surgery from 2009 till 2010. Our cases blindly will divide to two groups, group of case (n=75) and group of control (n=75) who will undergo spinal anesthesia. Participants including major eligibility criteria: Patients who will candidate for orthopedic lower limb surgery will include in our study. Patients with ASA class 3 and 4; and patients with contraindication for spinal anesthesia such as hemodynamic instability; refuse from spinal anesthesia; infection in site of spinal; raised CSF pressure and sensitivity to drugs will exclude from our study. Intervention: group one will undergo spinal block with 7.5 mg bupivacaine 0.5% and 5 µg sufentanil and group two will undergo spinal block with 15 mg bupivacaine 0.5%. Main outcome: Two groups will compare based on hypotension, need to use vasopressor, beginning of sensory block and its level and time of regression of the sensory level, pain during of surgery, duration of motor block, nausea, pruritus, vomiting and arrhythmia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012233954N6**
Registration date: **2011-06-06, 1390/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-06, 1390/03/16

Registrant information

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Mohammad Hossein Bakhshaei
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

Expected recruitment start date

2009-12-22, 1388/10/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial for comparison of effect of small dose of bupivacaine and sufentanil and normal dose of bupivacaine on hemodynamic variables in patients that underwent lower limb orthopedic surgery

Public title
effects of spinal anesthesia with small dose of bupivacaine and sufentanil
Purpose
Treatment
Inclusion/Exclusion criteria
Patients who candidate for orthopedic lower limb surgery included in our study. Patients with ASA class 3 and 4; patients with contraindication for spinal anesthesia such as hemodynamic instability; refuse from spinal anesthesia; infection in site of spinal; raised CSF pressure and sensitivity to drugs excluded from our study.
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **150**
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
Ethical Committee of Hamedan University of Medical Scienses
Street address
Hamedan University of Medical Scienses
City
Hamedan
Postal code
Approval date
2009-12-16, 1388/09/25
Ethics committee reference number
16/35/9/176709/پ

Health conditions studied

1

Description of health condition studied
spinal anesthesia
ICD-10 code
T88.7
ICD-10 code description
Unspecified adverse effect of drug or medicament

Primary outcomes

1

Description
Blood Pressure
Timepoint
1,3,5,10,15,30,60 min
Method of measurement
NIBP

Secondary outcomes

1

Description
need to catecholamine
Timepoint
time of need to catecholamine
Method of measurement
treatment of hypotension

2

Description
onset of sensory block
Timepoint
2 min iterval
Method of measurement
Pinprick test

3

Description
Maximum of sensory block
Timepoint
2 min iterval
Method of measurement
Pinprick test

4

Description
Time of sensory block till T10
Timepoint
2 min iterval
Method of measurement
Pinprick test

5

Description
Pain during operation
Timepoint
each time during operation
Method of measurement
request of patient

6

Description
Nausea
Timepoint
during operation
Method of measurement
subjective

7

Description
vomiting
Timepoint
during operation
Method of measurement
subjective

8

Description
Purities
Timepoint
during operation
Method of measurement
subjective

9

Description
Intraoperative Bleeding
Timepoint
during operation
Method of measurement
mm

Intervention groups

1

Description
Case group with 75 patients underwent spinal anesthesia with 7.5 mg bupivacaeine 0.5% and 5 µg sufentanil and 0.5 mm saline.
Category
Treatment - Drugs

2

Description
control group: 75 cases that underwent spinal block with 15 mg bupivacaine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital, Hamedan Univerity of Meical Sciences, Hamedan, Iran
Full name of responsible person
Mahmood Karbasfroushan
Street address
Blvd. Besat - Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hamedan University of Medical Sciences
Full name of responsible person
Dr. Ali Ghaleiha
Street address
Hamedan; Hamedan University of Medical Sciences
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Hamedan
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, Hamedan 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
Anesthesia and critical care department, Besat hospital, Hamedan Univerity of Meical Sciences, Hamed
Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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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