

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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 undergo 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 hemodynamic, 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

Name

Mohammad Hossein Bakhshaei

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1826 9403

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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 Sciences

Street address

Hamedan University of Medical Sciences

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 interval

Method of measurement

Pinprick test

3**Description**

Maximum of sensory block

Timepoint

2 min interval

Method of measurement

Pinprick test

4**Description**

Time of sensory block till T10

Timepoint

2 min interval

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 bupivacaine 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 University of Medical 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

City

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 University of Medical Sciences, Hamedan

Full name of responsible person

Mahmood Karbasfroushan

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Other areas of specialty/work

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Name of organization / entity

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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