

# 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)

###### Phone

+98 81 1826 9403

###### Email address

bakhshaei@umsha.ac.ir

##### 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

##### **Position**

Resident

##### **Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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**Position**

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## Person responsible for updating data

**Contact**

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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*