

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of co-administration of clonidine and pethidine with bupivacaine during spinal anesthesia

#### Protocol summary

##### Summary

This randomized double blind controlled trial was conducted to investigate the effects of co-administration of clonidine and pethidine with bupivacaine during spinal anesthesia. Fifty patients, in class 1 or 2 ASA, candidates for surgery on lower limbs, were randomly allocated in two groups and received either spinal anesthesia with combination of Clonidine 0.75 µg/kg and Pethidine 0.75 mg/kg) or spinal anesthesia with Bupivacaine 0.5%, 15 mg. Systolic blood pressure, heart rate, level of sensory block, motor block, and sedation rate were measured every 2 minutes at the first 10 minutes, every 3 minutes at the next 10 minutes, and every 5 minutes for the next 160 minutes. Analgesic requests were also recorded every 1 hour for 24 hours.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903013991N1**

Registration date: **2009-03-21, 1388/01/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-03-21, 1388/01/01

##### Registrant information

###### Name

Reza Salmanian

###### Name of organization / entity

Iran university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2271 5234

##### Email address

salmanian@irimc.org

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2009-03-21, 1388/01/01

##### Expected recruitment end date

2010-03-20, 1388/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of co-administration of clonidine and pethidine with bupivacaine during spinal anesthesia

##### Public title

Comparison of co-administration of clonidine and pethidine with bupivacaine during spinal anesthesia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients in class I or II ASA are selected for surgery in lower limbs at Rasoule akram Hospital.

Exclusion criteria: Any known contraindication for spinal anesthesia, such as increased intracranial pressure, neurological disorders, hemorrhagic diathesis, or infection at the puncture site, disorientation, bilateral lower limb Fx., pelvic Fx., diabetes mellitus, mitral stenosis, aortic stenosis, allergy to bupivacaine or clonidine or pethidine.

##### Age

From **15 years** old to **50 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## 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

Iran University of Medical Sciences

##### Street address

Hemmat Expway, Iran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2009-02-21, 1387/12/03

#### Ethics committee reference number

4399

## Health conditions studied

### 1

#### Description of health condition studied

Spinal anesthesia

#### ICD-10 code

Y48.4

#### ICD-10 code description

Anaesthetic, unspecified

## Primary outcomes

### 1

#### Description

Systolic Blood Pressure

#### Timepoint

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

#### Method of measurement

With automatic BP indicator

### 2

#### Description

Level of sensory block

#### Timepoint

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

#### Method of measurement

Evaluation for level of sensory block at different dermatome with blunt needle fo e

### 3

#### Description

Motor Block

#### Timepoint

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

#### Method of measurement

1=unable to move hip, 2=unable to move knee and 3=unable to move foot

### 4

#### Description

Sedation rate

#### Timepoint

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

#### Method of measurement

0=anxiet, 1=awake and calm, 2=Sleepy, 3=Sleepy and responsive to sound, 4=Sleepy and responsive to painfull stimuli, 5=Unresponsive

### 5

#### Description

Heart rate

#### Timepoint

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

#### Method of measurement

ECG monitoirg

### 6

#### Description

Analgesic request

#### Timepoint

Every 1 hour for 24 hours

#### Method of measurement

Patient's request

## Secondary outcomes

### 1

#### Description

Vomitting

#### Timepoint

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

#### Method of measurement

Observation

2

**Description**

Bradycardia

**Timepoint**

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

**Method of measurement**

ECG monitoirg

3

**Description**

Nausea

**Timepoint**

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

**Method of measurement**

Observation

4

**Description**

Hypotension

**Timepoint**

First 10 minutes: every 2 minutes, next 10 minutes: every 3 minutes and next 160 minutes: every 5 minutes

**Method of measurement**

Observation on Monitoring of Blood pressur indicator

## Intervention groups

1

**Description**

Spinal anesthesia with 15 mg Bupivacaine 0.5%

**Category**

Treatment - Drugs

2

**Description**

Spinal anesthesia with 0.75 mg/kg pethidine + 0.75 microgram/kg clonidine

**Category**

Treatment - Drugs

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Rasoule akram Hospital

**Full name of responsible person**

Reza Salmanian (Anesthesia resident)

**Street address**

Satarkhan ave. Niayesh st.

**City**

Tehran

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Science

**Full name of responsible person**

Farnad Imani

**Street address**

Niayesh st., Satarkhan Ave.

**City**

Tehran

**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 Science

**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**

Iran university of medical sciences

**Full name of responsible person**

Reza Salmanian

**Position**

Resident of Anesthesiology

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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**Position**

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[http://www.iums.ac.ir/index.php?slc\\_lang=en&sid=72](http://www.iums.ac.ir/index.php?slc_lang=en&sid=72)

**Person responsible for updating data****Contact****Name of organization / entity**

Iran university of medical sciences

**Full name of responsible person**

Reza Salmanian

**Position**

Resident of anesthesiology

**Other areas of specialty/work****Street address**

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**City**

Tehran

**Postal code****Phone****Fax****Email**

salmanian@gmail.com

**Web page address****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*