

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Full name of responsible person

Reza Salmanian

Position

Resident of anesthesiology

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

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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