Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of co-administration of clonidine and pethdine 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 pethdine 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 µgr/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 siences

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Iran (Islamic Republic of)

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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 pethdine with bupivacaine during spinal anesthesia

Public title
Comparison of co-administration of clonidine and pethdine 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, miteral 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
Bradicardia
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
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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