Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of Sufentanil in combination with Bupivacaine or Epinephrine and Bupivacaine alone in patients under spinal anesthesia on onset and recovery of motor and sensory block for lower extremity surgeries

Protocol summary

Summary

The aim of this study is comparison of the effect of Sufentanil in combination with Bupivacaine or Epinephrine and Bupivacaine alone in patients under spinal anesthesia on onset and recovery of motor and sensory block for lower extremity surgeries. In this double blind randomized clinical trail study ninety patients computerized divided into equal tree groups. inclusion criteria: patients with lower extremity surgery; patients classified in American association of anesthesiologist one and tow groups; all patients between 18 to 50 years old. exclusion criteria: all patients reject spinal anesthesia; shock; sepsis; fever; coagulation system dysfunction; opium addiction; local infection in site of spinal needle insertion. spinal anesthesia perform in the first group with fifteen milligrams of bupivacaine adding 5 micrograms of sufentanil, in second group fifteen milligrams of bupivacaine adding ten microgram epinephrine and in the third group fifteen milligrams of bupivacaine adding one milliliter normal saline as a placebo. after spinal anesthesia sensory and motor block is measure every one minutes for 20 minutes and onset of sensory block, onset of motor block note. recovery from sensory block and recovery from motor block are measure after one hour after start for every 5 minutes and note. also six hour after surgery pain is measure with visual analog scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050717607N1**
Registration date: **2015-08-16, 1394/05/25**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-08-16, 1394/05/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Birjand University Of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Sufentanil in combination with Bupivacaine or Epinephrine and Bupivacaine alone in patients under spinal anesthesia on onset and recovery of motor and sensory block for lower extremity surgeries

Public title
comparsion of the effect of bupivacaine in combination with sufentanil and epinephrine in patients under spainal anesthesia
Purpose
Other
Inclusion/Exclusion criteria
inclusion criteria: patients with lower extremity surgery; patients classified in American association of anesthesiologist one and tow groups; all patients between 18 to 50 years old. exclusion criteria: all patients reject spinal anesthesia; shock; sepsis; fever; coagulation system dysfunction; opium addiction; local infection in site of spinal needle insertion.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Birjand University of Medical Sciences
Street address
N:56, Ghafari Ave.
City
Birjand
Postal code
1973456783421589
Approval date
2014-11-30, 1393/09/09
Ethics committee reference number
1393-09-04

Health conditions studied

1

Description of health condition studied
Fracture of lower leg, including ankle
ICD-10 code
S82
ICD-10 code description
Fracture of lower leg, including ankle

Primary outcomes

1

Description
onset of sensory block
Timepoint
every minutes after spinal anesthesia for twenty minutes
Method of measurement
stopwatch

2

Description
onset of motor block
Timepoint
every minutes after spinal anesthesia fot twenty minutes
Method of measurement
stopwatch

3

Description
recovery from sensory block
Timepoint
every five minutes one houre after spinal anesthesia
Method of measurement
stopwatch

4

Description
recovery from motor block
Timepoint
every five minutes one houre after spinal anesthesia
Method of measurement
stopwatch

Secondary outcomes

1

Description
pain
Timepoint
six hours after end of surgery
Method of measurement
visual analog scale

Intervention groups

1

Description
fifteen milligrams of bupivacaine adding one milliliter normal saline intrathecal
Category
Placebo

2

Description
fifteen milligrams of bupivacaine adding five micrograms of sufentanil intrathecal
Category
Treatment - Drugs

3

Description
fifteen milligrams of bupivacaine adding ten micrograms epinephrine intrathecal
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Pooya Derakhshan
Street address
Imam Reza Hostipal, Taleghani St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Pooya Derakhshan
Street address
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City
Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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

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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