Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the level and duration of anesthesia and analgesia in usual and unilateral spinal punctures

Protocol summary

Summary

The purpose of this study is to compare the level and duration of anesthesia and analgesia in the usual and unilateral spinal puncture techniques. This research is a randomized and double-blind clinical trial which 96 patients were divided into the equal three groups. Group A received 10 mg Bupivacaine % 5/0 (2cc) in the sitting position at the L4-L3 or L4-L5 with Quincke needle size 24 within the cranial direction of needle in 10 seconds then the patient was rapidly being laid and operation started 15 minutes after. Group B received 10 mg Bupivacaine % 5/0 (2cc) in lateral decubitus position with the same site, needle and size in 30 seconds while the side of surgery was at bottom (dependent) through hole needle shifted to the bottom. Patients would remain 15 minutes in lateral position and they were operated in supine position. Group C received 8 mg of Bupivacaine % 5/0 (1/6CC) in lateral decubitus position as same as the second group. Then blood pressure, heart rate, level of anesthesia block, analgesia level, the level of sympathetic block, motor block level were measured as the baseline also they would be checked every 15 minutes to an hour after spinal punctures. Major inclusion criteria consist of patients between 20 and 60 years old; have been chosen electively for lower extremities surgery; in the ASA class I and II. Major exclusion criteria consist of patients didn't sign the written consent; contraindicated patients for spinal anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090114333N6**
Registration date: **2013-10-11, 1392/07/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-10-11, 1392/07/19

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 1821 4653
Email address
fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the level and duration of anesthesia and analgesia in usual and unilateral spinal punctures

Public title

Comparison of the level and duration of anesthesia and analgesia in usual and unilateral spinal punctures

Purpose

Treatment

Inclusion/Exclusion criteria
Major inclusion criteria: consist of patients between 20 and 60 years old; have been chosen electively for lower extremities surgery; in the ASA class I and II. Major exclusion criteria: consist of patients weren't in ASA class I and II; didn't sign the written consent; contraindicated patients for spinal anesthesia.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **92**
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
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2013-05-04, 1392/02/14
Ethics committee reference number
4801/7/420/پ

Health conditions studied

1

Description of health condition studied
spinal anesthesia
ICD-10 code
O74
ICD-10 code description
Complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
blood pressure
Timepoint
In first five minutes every two minutes ,after every 5 minutes to an hour in all three groups
Method of measurement
by monitoring device

2

Description
heart rate
Timepoint
In first five minutes every two minutes after every 5 minutes to an hour in all three groups.
Method of measurement
by monitoring device

3

Description
Level of anesthesia
Timepoint
In first five minutes every two minutes ,after every 5 minutes to an hour in all three groups.
Method of measurement
contact of cotton with skin

4

Description
Level of analgesia
Timepoint
Every 15 minutes to an hour after spinal
Method of measurement
pinprick test

5

Description
Level of motor block
Timepoint
In first five minutes every two minutes ,after every 5 minutes to an hour in all three groups
Method of measurement
Modified bromage test

6

Description
duration of analgesia
Timepoint
Every 15 minutes to an hour after spinal
Method of measurement
visual Analouge Scale (Vas)

7

Description
Level of sympathetic block
Timepoint
In first five minutes every two minutes ,after every 5 minutes to an hour in all three groups.
Method of measurement
alcoholic cotton

8

Description
Duration of anesthesia
Timepoint
In first five minutes every two minutes,after every 5 minutes to an hour in all three groups
Method of measurement
Interval Between Spinal Block to decrease to dermatomes

Secondary outcomes

empty

Intervention groups

1

Description
Group A: received 10 mg Bupivacaine % 5/0 (2cc) in the sitting position at the L4-L3 or L4-L5 with Quincke needle size 24 within the cranial direction of needle in 10 seconds then the patient was rapidly being laid and operation started 15 minutes after.
Category
Treatment - Drugs

2

Description
Group B: received 10 mg Bupivacaine % 5/0 (2cc) in lateral decubitus position with the same site, needle and size in 30 seconds while the side of surgery was at bottom (dependent) through hole needle shifted to the bottom. Patients would remain 15 minutes in lateral position and they were operated in supine position.
Category
Treatment - Drugs

3

Description
Group C: received 8 mg of Bupivacaine % 5/0 (1/6CC) in lateral decubitus position as same as the second group. Treatment: drugs
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr. Khalil Bakhtiar Zade
Street address
Emam Reza Hospital,Razi Boulvard,Sorkhleje
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Mitra Yari
Position
Anesthesiologist
Other areas of specialty/work
Street address

Emam Reza Hospital,Razi Boulvard,Sorkhleje

City

Kermanshah

Postal code

Phone

+98 83 1427 6309

Fax

Email

myari@kums.ac.ir

Web page address

Person responsible for updating data

Contact

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