Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the level of sensory blockage in spinal anesthesia with bupivacaine %0.5 and lidocaine %5 in surgical patients in Karaj Shahid madani and Bahonar hospital

Protocol summary

Summary

The aim of this study is to compare the level of sensory blockage in spinal anesthesia with bupivacaine %0.5 and lidocaine %5 in surgical patients. Study is a double blind randomized clinical trial. Patients who are candidates for spinal anesthesia and over 16 years old, estimated maximum operation duration until 90 minutes, body mass index(BMI) less than 30 Kg/m2, no history of aspirin and anticoagulant drugs administration at 7 days prior to surgical operation, without columnar deformity, no history of surgical operation on lumbar area, no abscess or infection on the insertion area of spinal needle, no lumbar disc herniation, no history of allergy to bupivacaine and lidocaine, migraine and chronic headache referring to operation room will select for study. pregnant patient, obesity patient with BMI more than 30kg/m2, patient with other than supine position, patient receiving hypnotic and opium drugs will exclude from study. Study population include all patient candidated for spinal anesthesia. sample size is 300 cases:will divide in two groups and each group include 150 cases. quincke spinal needle no 25 insert to L3-L4 interspinous space at sitting position. Lidocaine %5-100mg and bupivacaine %0.5- 15mg will inject in subarachnoid space then patients lie at supine position. intervention time will be 8 months. Pin prick test assessment is done for determination of sensory block level every 5 minutes by needle no 23

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012416338N1**
Registration date: **2014-07-24, 1393/05/02**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-07-24, 1393/05/02

Registrant information

Name
Seyyed Mohsen Pouryaeghobi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Sciences

Expected recruitment start date

2014-03-06, 1392/12/15

Expected recruitment end date

2014-09-06, 1393/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the level of sensory blockage in spinal anesthesia with bupivacaine %0.5 and lidocaine %5 in surgical patients in Karaj Shahid madani and Bahonar hospital

Public title

Spreading of anesthesia at spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterias: Adult patients over 16 years old؛ maximum surgery duration 150 minutes؛ body mass index(BMI) less than 30 kg/m2؛ without history of taking aspirin and any anticoagulant drugs at 1 week before surgery؛ without spine columnar deformity؛ no history of any surgery at lumbar area؛ without abscess or infection at spinal needle insertion area؛ no involve to lumbar disc herniation؛ no history of allergy to lidocaine and bupivacaine؛ no history of migraine and chronic headache Exclusion criteria: pregnant patients؛ obesity patients with BMI more than 30kg/m2؛ patient with other than supine position؛ patient receiving hypnotic and opium drugs

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

N/A

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

Alborz University of Medical Science

Street address

Shahrak-e-edari, North Taleghani Ave.

City

Karaj

Postal code

Approval date

2013-12-24, 1392/10/03

Ethics committee reference number

2303995

Health conditions studied

1

Description of health condition studied

Spinal anesthesia sensory blockade level

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bupivacaine

Timepoint

8 months

Method of measurement

mg

2

Description

Lidocaine

Timepoint

8 months

Method of measurement

mg

Secondary outcomes

1

Description

Sensory blockade level

Timepoint

each 5 minutes

Method of measurement

dermatomes anesthsia test

Intervention groups

1

Description

injection of lidocaine%5-100mg into CSF for spinal anesthesia done

Category

Prevention

2

Description

injection of bupivacaine %0.5-15mg into CSF for spinal anesthesia done

Category

Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
dr.emad addin mohsen
Street address
Shahid Madani Sq. Jahan shahr
City
Karaj

2

Recruitment center
Name of recruitment center
Shahid Bahonar Hospital
Full name of responsible person
Dr. elahi seyyed ahmad
Street address
Kaj Blv.
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Science
Full name of responsible person
Ali
Street address
Shahrak -e-edari,North Naleghani Ave.
City
Karaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz 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