

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3253 3488

Email address

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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

Name of organization / entity

Alborz University of Medical Science

Full name of responsible person

Dr. pouryaeghobi seyyed mohsen

Position

Anesthesiologist

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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