Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the level of sensory-motor effect of bupivacaine 5/0% with lidocaine5% in spinal anesthesia

Protocol summary

Summary

The aim of this study was Comparing the level of sensory-motor effect of bupivacaine 5/0% and lidocaine5% in spinal anesthesia. In a double-blind clinical trial, 64 patients were undergoing spinal anesthesia were randomize into two groups. Inclusion criteria: Patients between 17 to 70 years old with lower limb fracture and; exclusion criteria: dissatisfaction of patient to participate in the spinal anesthesia. Group1: 3ml of hyperbaric bupivacaine 0.5%; group 2: 2ml of hyperbaric lidocaine5%. In the determined minutes, hemodynamic changes and sensory and motor levels (abdominal, knee and ankle) have been measured in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012073010340N5**
Registration date: **2012-09-13, 1391/06/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-13, 1391/06/23

Registrant information

Name

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Name of organization / entity

Golestan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Golestan university of medical sciences

Expected recruitment start date

2010-03-16, 1388/12/25

Expected recruitment end date

2012-05-14, 1391/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the level of sensory-motor effect of bupivacaine 5/0% with lidocaine5% in spinal anesthesia

Public title

Comparing the level of sensory-motor between two drugs (lidocaine5% and bupivacaine0.5%) in spinal anesthesia

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 17 to 70 years old with lower limb fracture with ASA class I and II. Exclusion criteria: dissatisfaction of patients to participate in the spinal anesthesia and those who are suffering from vertigo and if the organs won’t get numb in spinal anesthesia.

Age

From **17 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **64**

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
Golestan university of medical sciences

Street address
Golestan university of medical sciences

City
Gorgan

Postal code

Approval date
2012-07-28, 1391/05/07

Ethics committee reference number
9100507167

Health conditions studied

1

Description of health condition studied
spinal anesthesia

ICD-10 code
T88.5

ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
level of sensoy

Timepoint
during surgery and recovery

Method of measurement
alcohol cotten

Secondary outcomes

1

Description
level of motor

Timepoint
during of surgery and recovery

Method of measurement
ask from patient

Intervention groups

1

Description
Group1: 3ml of hyperbaric bupivacaine 0.5% was injected

Category
Other

2

Description
Group2: 2ml of hyperbaric lidocaine5% was injected

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
5th azar hospital

Full name of responsible person

Street address

City
Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Golestan University of Medical Science

Full name of responsible person
Dr. Mohammad Vakili (Director of Research and Technology)

Street address
Kilometer 2 of road of Sari, Golestan University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Golestan 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

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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