

# 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

aryaie@goums.ac.ir

#### 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.

#### 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

#### 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

Mohammad Aryaie

#### Name of organization / entity

Golestan University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 911 277 1798

#### Email address

#### 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 sensory

#### Timepoint

during surgery and recovery

#### Method of measurement

alcohol cotton

## 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

##### City

Gorgan

#### 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

### Contact

**Name of organization / entity**  
5th of azar hospital  
**Full name of responsible person**  
Kazem Kazem nejad  
**Position**  
anesthesiologist  
**Other areas of specialty/work**  
**Street address**  
5th of azar hospital, 5azar street, Kakh squire  
**City**  
Gorgan  
**Postal code**  
**Phone**  
+98 17 1277 1798  
**Fax**  
**Email**  
kazemnejad1341@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Golestan university of medical sciences  
**Full name of responsible person**  
Mohammad Aryaie  
**Position**  
master degree  
**Other areas of specialty/work**  
**Street address**  
5th of azar hospital  
**City**

Gorgan  
**Postal code**  
**Phone**  
+98 17 1442 1651  
**Fax**  
**Email**  
aryaie2009@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
golestan university of medical science  
**Full name of responsible person**  
Amin Hasanzad  
**Position**  
bachelor degree  
**Other areas of specialty/work**  
**Street address**  
5th azar hospital  
**City**  
Gorgan  
**Postal code**  
**Phone**  
+98 17 1995 6327  
**Fax**  
**Email**  
amin\_hassanzad@yahoo.com  
**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*