

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 Analogue 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 Boulevard,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 Boulevard,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*