

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### comparision of hemodynamic changes in elderly patients undergoing orthopedic surgery of the lower limbs in tow ways subarachnoid bupivacain and subarachnoid meperidin

#### Protocol summary

##### Summary

This study will be done with aim to comparative investigation of hemodynamic changes in elderly patients undergoing orthopedic surgery of the lower limbs in two subarachnoid bupivacain and subarachnoid meperidin ways. This study is one-blinded clinical trial. The study population will be included all elderly patients undergoing orthopedic surgery of the lower limbs at least one year in Imam Reza and Taleghani hospitals of Kermanshah. The total of 66 patients will be selected in available method and randomly will be assigned in to two experimental groups. In the first group anesthesia with bupivacaine spinal, the patient is placed in a sitting position and by spinal needle number 15-25,12.5-24 mg of bupivacaine half percent (0.5 %) (2.5 ml) in subarachnoid space (between vertebrae 12-13and 13-14 ) injection is done. In the second group the patient is placed in a sitting position and by spinal needle number 24-25 pethidine With the dose of 1 mg plus 2 ml csf in the subarachnoid space (between the vertebrae 12-13 and 13-14) will be injected. First, during, and after the end of the study, both groups are compared in terms of hemodynamic changes. Inclusion criteria: Age over 60 years; Patients of class 1 and 2 ASA-PS. Exclusion criteria: Patients who consume narcotic drugs and psychotropic substances; patients generally have a contraindication to spinal procedures; Patients who experience severe pain during the surgery and have to use general anesthesia.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017031414333N71**  
Registration date: **2017-04-06, 1396/01/17**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-06, 1396/01/17

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2017-05-10, 1396/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparision of hemodynamic changes in elderly patients undergoing orthopedic surgery of the lower limbs in tow ways subarachnoid bupivacain and subarachnoid meperidin

## Public title

Comparison of changes in blood pressure and heart rate in patients undergoing orthopedic surgery of the lower limbs in two anesthesia method.

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Age over 60 years; Patients of class 1 and 2 ASA-PS. Exclusion criteria: Patients who consume narcotic drugs and psychotropic substances; patients generally have a contraindication to spinal procedures; Patients who experience severe pain during the surgery and have to use general anesthesia.

## Age

From **60 years** old to **100 years** old

## Gender

Both

## Phase

1-2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **66**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Building No.2, ShahidBeheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### City

Kermanshah

##### Postal code

#### Approval date

2017-03-08, 1395/12/18

#### Ethics committee reference number

kums.rec.1395.759

## Health conditions studied

### 1

#### Description of health condition studied

Fracture of Lower Limb

#### ICD-10 code

T12

#### ICD-10 code description

Fracture of lower limb, level unspecified

## Primary outcomes

### 1

#### Description

Itching

#### Timepoint

First, during, and after the end of the study

#### Method of measurement

Based on patient interview

### 2

#### Description

Nausea and vomiting

#### Timepoint

First, during, and after the end of the study

#### Method of measurement

Based on patient interview

### 3

#### Description

Urinary retention

#### Timepoint

First, during, and after the end of the study

#### Method of measurement

Based on patient interview

### 4

#### Description

Respiratory depression

#### Timepoint

First, during, and after the end of the study

#### Method of measurement

Based on the questions of the patient and a doctor diagnoses

### 5

#### Description

Duration of analgesia

#### Timepoint

The first, second, third, fourth, fifth, sixth hours after the start of the study

#### Method of measurement

Based on the questions of the patient and a doctor diagnoses

### 6

#### Description

Hemodynamic changes

## Timepoint

First, during, and after the end of the study

## Method of measurement

Based on manometer and monitor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the first group anesthesia with bupivacaine spinal, the patient is placed in a sitting position and by spinal needle number 15-25, 12.5-24 mg of bupivacaine half percent (0.5 %) (2.5 ml) in subarachnoid space (between vertebrae 12-13 and 13-14 ) injection is done.

#### Category

Treatment - Drugs

### 2

#### Description

In the second group the patient is placed in a sitting position and by spinal needle number 24-25 pethidine with the dose of 1 mg plus 2 ml csf in the subarachnoid space (between the vertebrae 12-13 and 13-14) will be injected.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

Dr. Hamzeh Hasani

##### Street address

Taleghani Hospital, Shahid Beheshti Blvd

##### City

Kermanshh

### 2

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Dr. Hamzeh Hasani

##### Street address

Emam Reza Hospital, Parastar Boulevard

##### City

Kermanshh

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

##### Full name of responsible person

Koroush Hamzehee

##### Street address

Building No.2, ShahidBeheshti, 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

Vice chancellor for research, 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

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Hamzeh Hasani

##### Position

Resident of Anesthesiology

##### Other areas of specialty/work

##### Street address

Faculty of medical, Parastar Boulevard

##### City

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##### Postal code

##### Phone

00

##### Fax

##### Email

hhasani95@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

**Full name of responsible person**

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**Position**

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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*