

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Study of the effect of lumbar arch support in the prevention of low back pain during spinal anesthesia: A clinical trial

#### Protocol summary

##### Study aim

Study of the effect of lumbar arch support in the prevention of low back pain during spinal anesthesia: A clinical trial

##### Design

This randomized clinical trial design is a parallel design with a control group. This randomized, phase 2-3 study will be performed on 154 patients undergoing surgery. A random number table is used for randomization and participants are assigned to intervention and control groups.

##### Settings and conduct

This study, which will be conducted in Imam Reza Hospital of Kermanshah, is a single-blinded one. In this single-blinded study, the outcome assessor is unaware of the allocation of individuals to intervention and control groups. Spinal anesthesia for all patients is performed by a specific person with a Quincke needle size 25 in a sitting position using bupivacaine 0.5%. All patients in both control and intervention groups use the same type of bed and mattress.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years old; Patient satisfaction; No history of mental illness. Exclusion criteria: Patients with a history of taking painkillers (opioids or non-opioids) in the recent week; Having symptoms of high intracranial pressure; Abnormal spinal anatomy such as scoliosis; Coagulation problems; Patients with low back pain under previous spinal anesthesia.

##### Intervention groups

In the intervention group, patients will be asked to place an air mattress under the lumbar vertebrae according to the anatomical position before surgery and after performing spinal anesthesia in the supine position until the anesthetic effect wears off. No intervention will be performed in the control group

##### Main outcome variables

Pain intensity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211019052817N1**

Registration date: **2021-11-13, 1400/08/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-13, 1400/08/22**

Update count: **0**

##### Registration date

2021-11-13, 1400/08/22

##### Registrant information

##### Name

Omid Bahiraei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3845 3254

##### Email address

o\_bahiraei@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-10, 1400/08/19

##### Expected recruitment end date

2022-02-08, 1400/11/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the effect of lumbar arch support in the prevention of low back pain during spinal anesthesia: A clinical trial

#### Public title

The effect of lumbar arch support in the prevention of low back pain during spinal anesthesia

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age over 18 years old Patient satisfaction No history of mental illness

##### Exclusion criteria:

Patients with a history of taking painkillers (opioids or non-opioids) or any drugs in one recent week. Having symptoms of high intracranial pressure Abnormal spinal anatomy such as scoliosis Coagulation problems Patients with low back pain during previous spinal anesthesia

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor

#### Sample size

Target sample size: **154**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Using a table of random numbers. Patients based on random numbers generated by the program (Excel version 2016 and RANDBETWEEN function) that values less than 5.0 (0.0009-0.000) will be assigned to the intervention group and more than 5.0 (0.500-999) will be assigned to the control group

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The project partner, who does not know how the volunteers are assigned in the groups, will evaluate the incidence and severity of low back pain in the project.

#### 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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6715847141

#### Approval date

2021-11-07, 1400/08/16

#### Ethics committee reference number

IR.KUMS.MED.REC.1400.055

### Health conditions studied

#### 1

##### Description of health condition studied

Low back pain

##### ICD-10 code

M54.5

##### ICD-10 code description

Low back pain

### Primary outcomes

#### 1

##### Description

Pain intensity

##### Timepoint

6 hours, 24 hours and 7 days after surgery

##### Method of measurement

The visual analog scale

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

In the intervention group, patients will be asked to place an air mattress under the lumbar vertebrae according to the anatomical position before surgery and after performing spinal anesthesia in the supine position until the anesthetic effect wears off.

##### Category

Treatment - Other

#### 2

##### Description

No intervention will be performed in the control group

##### Category

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Dr. Omid Bahiraei

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

omidbahirae@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Reza Khodarahmi

**Street address**

Vice Chancellor for Research Affairs, Kermanshah  
University of Medical Sciences, Building No.2, Shahid  
Beheshti Boulevard

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rkhodarahmi@kums.ac.ir

**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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Omid Bahiraei

**Position**

Resident anesthesia

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Emam Reza Hospital, Parastar Boulevard

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Javad Amini Saman

**Position**

Faculty member of Kermanshah University of Medical  
Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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aminisaman399@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Omid Bahiraei

**Position**

Resident anesthesia

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available