

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 Quinke 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

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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
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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

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

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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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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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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