Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of epidural gelfoam soaked in bupivacaine and intramuscular paravertebral bupivacaine on postoperative analgesia after lumbar spine surgeries

Protocol summary

Study aim

Comparison of the effects of epidural gelfoam soaked in bupivacaine and intramuscular paravertebral bupivacaine on postoperative analgesia after lumbar spine surgeries

Design

A randomized, double-blind, parallel-group, Phase 3 clinical trial will be conducted in 60 patients. Randomization will be performed using block randomization method using Random allocation software.

Settings and conduct

This study will be conducted on patients undergoing lumbar spine surgery with general anesthesia in Urmia Imam Khomeini Hospital. For patients in the first group, a 1 × 5 cm strip of gelfoam soaked in 70 mg of 0.25% bupivacaine will be placed in the epidural space 30 minutes before wound closure following laminectomy. For patients in the second group, 70 mg of 0.25% bupivacaine will be injected intramuscularly paravertebrally 30 minutes before wound closure. The study will be conducted as a single-blind clinical trial, and patients will be unaware of their assignment to one of the intervention groups.

Participants/Inclusion and exclusion criteria

In this study, 60 patients aged 18 to 65 years undergoing lumbar spine surgery under general anesthesia will be included. The main exclusion criteria include patients with a body mass index (BMI) over 30 kg/m2, a history of seizures, severe systemic disease, coagulation disorders, and drug abusers.

Intervention groups

For patients in the first group, a 1 × 5 cm strip of gelfoam soaked in 70 mg of 0.25% bupivacaine will be placed in the epidural space 30 minutes before wound closure following laminectomy. For patients in the second group, 70 mg of 0.25% bupivacaine will be injected intramuscularly paravertebrally 30 minutes before wound closure.

Main outcome variables

Pain severity; time of first request for analgesic medication; dosage of morphine analgesic medication.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230520058233N1**
Registration date: **2023-07-11, 1402/04/20**
Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**
Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

Peyman Gholipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

gholipour.p@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of epidural gelfoam soaked in bupivacaine and intramuscular paravertebral bupivacaine on postoperative analgesia after lumbar spine surgeries

Public title
The effects of epidural gelfoam soaked in bupivacaine and intramuscular paravertebral bupivacaine on postoperative analgesia after lumbar spine surgeries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing lumbar spine surgery with general anesthesia Age between 18 and 65 years old Patients with physical status one and two according to the criteria of the American Anesthesia Association (ASA I, II)
Exclusion criteria:
Body mass index above 30 kg/m2 History of seizure disorder Severe systemic disease Coagulation disorders Drug abusers
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to two groups using the Block Randomization method based on generated-numbers by the Random Allocation computer software. In this software, the number of groups and the total sample size will be entered first, and then the Block randomization method will be implemented in the block section. Therefore, based on the total sample size (60 patients), 15 blocks of four will be used.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study will be conducted as a single-blind clinical trial. The patients will be blind of their allocation in one of intervention groups. So, the table of computer-generated numbers will be given to the physician. The physician will enter the patients into groups according to the order of numbers.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Imam Khomeini Hospital, Urmia University of Medical Sciences.
Street address
Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
57157-89397
Approval date
2023-05-14, 1402/02/24
Ethics committee reference number
IR.UMSU.HIMAM.REC.1402.023

Health conditions studied

1

Description of health condition studied
Analgesia after lumbar spine surgeries
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain severity
Timepoint
In recovery and 6, 12 and 24 hours after the surgery
Method of measurement
Visual analogue scale (VAS)

2

Description
Time of first request for analgesic medication
Timepoint
In 24 hours after the surgery
Method of measurement
Time of request by the patient

3

Description

Dosage of morphine analgesic medication

Timepoint

In 24 hours after the surgery

Method of measurement

Miligeram

Secondary outcomes

1

Description

Mean arterial blood pressure

Timepoint

In recovery and 6, 12 and 24 hours after the surgery

Method of measurement

Monitoring by device

2

Description

Heart rate

Timepoint

In recovery and 6, 12 and 24 hours after the surgery

Method of measurement

Monitoring by device

Intervention groups

1

Description

Intervention group: For patients in the first group, a 1 × 5 cm strip of gelfoam soaked in 70 mg of 0.25% bupivacaine will be placed in the epidural space 30 minutes before wound closure following laminectomy.

Category

Treatment - Drugs

2

Description

Intervention group: For patients in the second group, 70 mg of 0.25% bupivacaine will be injected intramuscularly paravertebrally 30 minutes before wound closure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini hospital

Full name of responsible person

Dr. Peyman Gholipour

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Peyman Gholipour

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurosurgery

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Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.
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Person responsible for scientific inquiries

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Latest degree
Subspecialist
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Person responsible for updating data

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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
Confidentiality of patient information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The results of the study will be published as an article.
When the data will become available and for how long
After publishing the article
To whom data/document is available
Researchers
Under which criteria data/document could be used
The results will be published as an article and the data will not be published
From where data/document is obtainable
Corresponding author email: gholipour.p@umsu.ac.ir
What processes are involved for a request to access data/document
By email address of the corresponding author:gholipour.p@umsu.ac.ir
Comments