

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### The effect of bilateral lumbar erector spine plane block on postoperative pain of lumbar laminectomy operation

#### Protocol summary

##### Study aim

the effect of bilateral lumbar erector spine plane block on postoperative pain of lumbar laminectomy operation

##### Design

Double blinded Randomized Clinical Trial

##### Settings and conduct

Patients in the intervention group sit in the sitting position at the operating theater and undergo transient ultrasonography of the lumbar vertebrae and with spinal needle 22, 20 cc of bupivacaine 0.25% is injected on each side of the lumbar spine, and then patients will be under general anesthesia. In the control group, 20 cc of bupivacaine 0.25% will injected on each side of the lumbar vertebra under general anesthesia.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients undergoing lumbar laminectomy surgery, age range of 18-65, (ASA = 1 or 2). patients who are mentally capable of cooperating with the study and answering questions. Exclusion criteria: Uncontrolled seizures, Depression, Local infection, Rupture and repair of dura, Severe coagulation disorder, Substance abuse and dependence, sensitivity to any of the drugs used in the study, Patients who need mechanical ventilation postoperatively, Patients with psychotic somatic pain

##### Intervention groups

Intervention group: Patients in the intervention group sit in the sitting position and undergo transient ultrasonography of the lumbar vertebrae and with spinal needle 22, 20 cc of bupivacaine 0.25% is injected on each side of the lumbar spine, and then patients will be under general anesthesia. In the control group, 20 cc of bupivacaine 0.25% will injected on each side of the lumbar vertebra under general anesthesia.

##### Main outcome variables

Pain severity, Patients Satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100127003213N6**

Registration date: **2019-07-07, 1398/04/16**

Registration timing: **prospective**

Last update: **2019-07-07, 1398/04/16**

Update count: **0**

##### Registration date

2019-07-07, 1398/04/16

##### Registrant information

##### Name

Arash Farbood

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1233 7636

##### Email address

farboda@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-21, 1398/04/30

##### Expected recruitment end date

2019-10-22, 1398/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of bilateral lumbar erector spine plane block on postoperative pain of lumbar laminectomy operation

## Public title

The effect of bilateral lumbar erector spine plane block on postoperative pain of lumbar laminectomy operation

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients undergoing lumbar laminectomy surgery. age range of 18-65. (ASA = 1 or 2). patients who are mentally capable of cooperating with the study and answering questions.

### Exclusion criteria:

Uncontrolled seizures Depression Local infection Rupture and repair of dura Severe coagulation disorder Substance abuse and dependence sensitivity to any of the drugs used in the study Patients who need mechanical ventilation post opeartively Patients with psychotic somatic pain

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using random numbers or the Randomizer.org site, patients fall into one of two B or C groups. The name of each patient's group will be readily available in closed envelopes by a staff member who already has access to the randomized list of patients.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants, such as anesthetist, anesthetist technician, surgeon, and those responsible for collecting data, are unaware of the patient's study group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

#### Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

#### City

Shiraz

#### Province

Fars

#### Postal code

7134844119

### Approval date

2019-01-31, 1397/11/11

### Ethics committee reference number

IR.SUMS.MED.REC.1397.602

## Health conditions studied

## 1

### Description of health condition studied

lumbar laminectomy operation

### ICD-10 code

M43.26

### ICD-10 code description

Fusion of spine, lumbar region

## Primary outcomes

## 1

### Description

Pain Severity

### Timepoint

Every 15 minutes (at intervals of 15-30-45-60 minutes) in the operating room and then in the ward every one hour at the first 6 hours , every 2 hours at the second 6 hours and every 4 hours after the next 12 hours.

### Method of measurement

Numerical Rating Scale

## 2

### Description

Patients Satisfaction

### Timepoint

24 hours after surgery

### Method of measurement

Likert Scale

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Patients in the intervention group sit in the sitting position and undergo transient ultrasonography of the lumbar vertebrae and with spinal needle 22, 20 cc of bupivacaine 0.25% is injected on each side of the lumbar spine, and then patients will be under general anesthesia.

### Category

Prevention

## 2

### Description

Control group: In the control group, 20 cc of bupivacaine 0.25% will be injected on each side of the lumbar vertebra under general anesthesia.

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Chamran Hospital

#### Full name of responsible person

Seeyed Amir Reza Akhlagh

#### Street address

Chamran Hospital, Chamran Boulevard

#### City

Shiraz

#### Province

Fars

#### Postal code

1564471948

#### Phone

+98 71 3624 0101

#### Email

chamranhosp@sums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr Yones Ghasemi

#### Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

#### City

Shiraz

#### Province

Fars

#### Postal code

7134844119

#### Phone

+98 71 3647 4270

#### Email

sacrc@sums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

#### Full name of responsible person

Seeyed Amir Reza Akhlagh

#### Position

Intern

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

#### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

#### City

Shiraz

#### Province

Fars

#### Postal code

7134844119

#### Phone

+98 71 3647 4270

#### Email

amirakhlagh@hotmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Arash Farbood

#### Position

Anesthesiologist/Pain Fellowship

#### Latest degree

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street

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**Postal code**

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+98 36474270

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arashfarbood@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Arash Farbood

**Position**

Anesthesiologist/Pain Fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street

**City**

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**Province**

Fars

**Postal code**

1564471948

**Phone**

+98 36474270

**Email**

arashfarbood@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available