Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 post opeartively,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 Satsfaction

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 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

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Shiraz

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1564471948

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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

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

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7134844119

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Arash Farbood

Position
Anesthesiologist/Pain Fellowship

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Arash Farbood
Position
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Latest degree
Subspecialist
Other areas of specialty/work
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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