Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Erector Spina Block with Ropivacaine and Erector Spina Block with Ropivacaine and Epinephrine on Intraoperative Bleeding and Duration of Analgesia in Posterior Lumbar Spine Fusion Surgery

Protocol summary

Study aim
Comparison of Erector Spina Block with Ropivacaine and Erector Spina Block with Ropivacaine and Epinephrine on Intraoperative Bleeding and Duration of Analgesia in Posterior Lumbar Spine Fusion Surgery

Design
Clinical trial with control and intervention group, single blind, on 64 patients, randomized with sealed envelope.

Settings and conduct
Patients referred to Luqman Hospital are divided into two intervention and control groups of 32 people by block randomization. After anesthesia with the same method, both groups will be placed in the prone position before the surgery under ultrasound guidance under bilateral erector spina block at the level of the surgical site. Paramedian sagittal ultrasound probe, about 2 cm outside the spinous processes, we find the transverse process on the same side. We insert the needle caudal to the cranial so that the tip of the needle hits the transverse process. If the needle site is suitable, 20 cc of ropivacaine 0.25% with 5 mic/ml of epinephrine will be injected in the intervention group and 20 cc of ropivacaine 0.25% in the control group. Isoflurane and opioid consumption ,bleeding, pain, in recovery, as well as at 1-6-12 and 24 hours after the operation are recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Patients 18-65 years old; Normal kidney and liver function; ASA score 1-2; Patient consent ; No history of allergies to local anesthetics; No drug addiction Exclusion criteria:, Increase the scope of surgery to more than three level ,time of surgery for more than 6 hours; No diabetes

Intervention groups
The intervention group, after anesthesia and changing to the prone position, ,are subjected to erector spinae block with Ropivacaine-epinephrine, and the control group are subjected to block with Ropivacaine

Main outcome variables
Consumption of isofluran , opioids, pain score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210415050983N12**
Registration date: **2025-06-24, 1404/04/03**
Registration timing: **prospective**

Last update: **2025-06-24, 1404/04/03**
Update count: **0**

Registration date
2025-06-24, 1404/04/03

Registrant information

Name
Sogol Asgari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8836 3185

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drasgari98429@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Erector Spina Block with Ropivacaine and Erector Spina Block with Ropivacaine and Epinephrine on Intraoperative Bleeding and Duration of Analgesia in Posterior Lumbar Spine Fusion Surgery

Public title
Comparison of Erector Spina Block with Ropivacaine and Erector Spina Block with Ropivacaine and Epinephrine on Intraoperative Bleeding and Duration of Analgesia in Posterior Lumbar Spine Fusion Surgery
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18-65 years old are candidates for two or three level spine surgery ASA score 1-2 Normal kidney and liver function Patient consent to perform the block No history of allergies to local anesthetics No drug addiction No diabetes
Exclusion criteria:
Increase the scope of surgery to more than three level Extending the length of surgery for more than 6 hours Block site or systemic infection History of anticoagulant use
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted Randomized Blocks :In this method, 10 random blocks are generated by computer. Each block includes 5 people in the intervention group and 5 people in the control group. The order of these people is randomly arranged by computer and people are assigned to groups in the same way. At the end of each block, a new block of 10 is produced and this process will continue until the final sample volume is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in the study are unaware of the groupings because the intervention is performed after anesthesia. The patient's clinical caregiver, the evaluator and recorder of the results, and the data analyzer are not aware of the grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice for Research and Technology, Shahid Beheshti University of Medical Sciences
Street address
Velenjak, Yemen Street, Shahid Shahriari Square
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2025-04-29, 1404/02/09
Ethics committee reference number
IR.SBMU.MSP.REC.1404.038

Health conditions studied

1

Description of health condition studied
Lumbar discopathy
ICD-10 code
M51.36
ICD-10 code description
Other intervertebral disc degeneration, lumbar region

Primary outcomes

1

Description
Intraoperative isoflurane Consumption in tow groups
Timepoint
Before the start of anesthesia and after the end of anesthesia
Method of measurement
By a graduated glass based on mL

2

Description
Intraoperative fentanyl consumption in the two groups
Timepoint
End of surgery
Method of measurement

Dosage consumed based on mcg

3

Description
Pain after surgery
Timepoint
0, 1 , 6 , 12 and 24 hours after surgery
Method of measurement
Numeric Rating Scale(NRS)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Control group: After anesthesia and change of position to peron before surgery, in sterile conditions, using peripheral nerve block needle (stimuQuik, ARROW use) with sonosite-Nerve Ultrasound system under the erector spina block One-sided and each-sided injection of 20 ml of 0.25% ropivacaine was performed by a trained anesthesiologist in accordance with standard guidelines.A 5-8MHz liner probe is used for nerve block ultrasound guides. After selecting the target process transducer, the sagittal paramedic prop is placed about 2 cm outside the spinous processes so that the process transducer can be seen in the same direction. Insert the needle inplean the codal from the cranial to cudal until the tip of the needle hits the process transducer. 1-2 cc of local anesthetic is injected to ensure the correct location of the needle. If the location of the needle is suitable, the medicine is injected. The needle point is towards the posterior and inferior side.
Category
Treatment - Drugs

2

Description
Intervention group: After anesthesia and change of position to peron before surgery, in sterile conditions, using peripheral nerve block needle (stimuQuik, ARROW use) with sonosite-Nerve Ultrasound system under the erector spina block One-sided and each-sided injection of 20 ml of ropivacaine 0.25% and 5 mic/mL epinephrin was performed by a trained anesthesiologist in accordance with standard guidelines.A 5-8MHz liner probe is used for nerve block ultrasound guides. After selecting the target process transducer, the sagittal paramedic prop is placed about 2 cm outside the spinous processes so that the process transducer can be seen in the same direction. Insert the needle inplean the codal from the cranial to cudal until the tip of the needle hits the process transducer. 1-2 cc of local anesthetic is injected to ensure the correct location of the needle. If the location of the needle is suitable, the medicine is injected. The needle point is towards the posterior and inferior side.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Sogol Asgari
Street address
South Kargar St. - Kamali St. - Special St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sogol Asgari
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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