

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 isoflurane , 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

Email address

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

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Velenjak, Yemen Street, Shahid Shahriari Square

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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

Treatment - Drugs

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 prone 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 inplane the codal from the cranial to caudal 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

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Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Sogol Asgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaei

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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

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Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

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