Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of erector spinae muscle block with direct visualization injection of 0.25% bupivacaine at the end of lumbar surgery on postoperative pain: a randomized clinical trial

Protocol summary

Study aim
Determining the effectiveness of erector spinae muscle blockade with direct visualization injection of 0.25 percent bupivacaine at the end of surgery for postoperative analgesia after lumbar laminectomy.

Design
This study is a randomized, double-blind, parallel-group clinical trial with a control group conducted on 90 patients. Allocation of participants to the intervention and control groups is performed using block randomization.

Settings and conduct
This study is a randomized, double-blind clinical trial conducted at Ayatollah Rouhani Hospital, Babol. Patients are allocated to the intervention and control groups using block randomization. At the end of surgery, an erector spinae muscle block is performed using either 0.25 percent bupivacaine or normal saline. Patient, surgeon, clinical staff, outcome assessor, data analyst, and anesthesiologist are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 65 years, lumbar laminectomy at a maximum of two levels between L1 and L5, no use of analgesic medications within 48 hours prior to surgery, No history of rheumatologic or musculoskeletal disorders, Body mass index less than or equal to 45

Intervention groups
Intervention group: At the end of lumbar laminectomy surgery, erector spinae block is performed using direct visualization injection of 0.25 percent bupivacaine (Aspen) with a total volume of 40 milliliters, administered as a single dose bilaterally, and performed once for each patient. Control group: Under similar conditions, erector spinae block is performed using direct visualization injection of normal saline with a total volume of 40 milliliters, administered as a single dose bilaterally, and performed once for each patient.

Main outcome variables
Postoperative lumbar pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251216068353N1**
Registration date: **2026-02-06, 1404/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-06, 1404/11/17**
Update count: **0**

Registration date
2026-02-06, 1404/11/17

Registrant information

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Meisam Ghorbanpoor

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of erector spinae muscle block with direct visualization injection of 0.25% bupivacaine at the end of lumbar surgery on postoperative pain: a randomized clinical trial

Public title
Effect of Erector Spinae Muscle Block with Bupivacaine on Postoperative Pain Following Lumbar Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years. Candidate for elective lumbar laminectomy surgery at a maximum of two levels between L1 and L5. Provision of written informed consent to participate in the study. No use of any analgesic medication within 48 hours before surgery. No history of rheumatologic or musculoskeletal disorders. No known allergy to bupivacaine or anesthetic drugs. Body mass index less than or equal to 45.
Exclusion criteria:
Inability to understand or reliably report pain intensity using the Visual Analog Scale (VAS) Presence of neurological disorders that affect pain perception, sensation, or motor function Presence of active infection, inflammation, or skin lesion at the planned erector spinae block injection site Documented coagulation disorders or use of anticoagulant medications that contraindicate regional anesthesia blocks Presence of severe and unstable systemic diseases that make regional analgesia unsafe
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are allocated to the intervention and control groups using block randomization. The unit of randomization is the individual participant, and all eligible patients enter the randomization process after confirmation of the inclusion criteria and obtaining written informed consent. Simple randomization or quasi-randomized methods are not used in this study. Randomization is performed using equal-sized blocks with a block size of 4 and an allocation ratio of 1:1 between the intervention and control groups. Stratified randomization is not applied in this study. The random allocation sequence is generated independently prior to study initiation using validated online random number generation tools (www.randomization.com or www.randomizer.org). The generated sequence, which defines the order of assignment to the two groups, is not accessible to the study execution team or outcome assessors.To ensure allocation concealment, each participant’s group assignment is recorded on a separate sheet and placed inside sequentially used, opaque, sealed envelopes labeled with a unique four-character code. Envelopes are opened in order and only after definitive enrollment of the participant and completion of all inclusion criteria, by the designated study executor. Participants, the clinical care team, researchers, outcome assessors, and data collectors are blinded to group allocation and type of intervention, thereby minimizing the risk of bias in treatment assignment and outcome assessment.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this randomized clinical trial, blinding is implemented to minimize allocation, performance, and assessment bias throughout the study. After receiving a full explanation of the study objectives and providing written informed consent, participants are enrolled in the trial; however, due to the use of general anesthesia and identical procedural steps in both groups, they remain unaware of the type of intervention allocated to them. Clinical care providers, including surgeons, anesthesiologists responsible for general anesthesia, operating room staff, ward nurses, and postoperative care personnel, are blinded to group allocation. To maintain blinding at the anesthesiology level, the erector spinae muscle block is performed by an experienced anesthesiologist who is a member of the research team but does not participate in general anesthesia management, intraoperative care, postoperative care, or outcome assessment. A second anesthesiologist, who is responsible for administering general anesthesia, is not informed about whether the block has been performed or which solution has been injected. In both the intervention and control groups, all preparation procedures, injection sites, and surgical dressings are standardized and identical, ensuring that no visible differences can reveal the assigned intervention. This approach prevents unintentional unblinding of patients and clinical staff. The principal investigator, co-investigators, research assistants, and outcome assessors are blinded to the treatment allocation and have no access to the randomization sequence. Outcome measures, including postoperative pain intensity assessed by the Visual Analogue Scale, opioid consumption, time to first request for analgesia, and functional outcomes, are collected by trained personnel who are unaware of group assignment. All collected data are analyzed using coded group labels, and the data analyst remains blinded to the intervention type until the final analysis is completed. No independent

Data Safety and Monitoring Committee is defined for this study due to its limited scale and low-risk nature.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Babol University of Medical Sciences

Street address

Ganjafrooz Street, Babol University of Medical Sciences

City

Babol

Province

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Postal code

۴۷۱۷۶۴۷۷۴۵

Approval date

2025-12-08, 1404/09/17

Ethics committee reference number

IR.MUBABOL.REC.1404.188

Health conditions studied

1

Description of health condition studied

Postoperative lumbar pain (lumbar laminectomy)

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Severity of postoperative pain measured using the Visual Analog Scale (VAS) during the first 24 hours after surgery

Timepoint

Postoperative pain severity will be measured using the Visual Analog Scale (VAS) after the intervention, immediately in the recovery period following the end of surgery, and subsequently at 2, 6, 12, and 24 hours after completion of lumbar surgery.

Method of measurement

Pain intensity is measured using the Visual Analogue Scale for pain assessment, in which zero represents no pain and ten represents the worst imaginable pain. All assessments are performed by a trained evaluator blinded to group allocation.

Secondary outcomes

1

Description

Time to first administration of intravenous analgesic after completion of lumbar surgery

Timepoint

From the end of surgery until administration of the first intravenous analgesic within the first 24 hours postoperatively.

Method of measurement

Recording the time of first intravenous analgesic administration according to nursing and medication records.

2

Description

Length of hospital stay after completion of lumbar surgery

Timepoint

From the completion of lumbar surgery until hospital discharge.

Method of measurement

Calculation of hospital stay based on recorded admission and discharge dates and times in medical records.

3

Description

Level of functional disability in activities of daily living during the first week after hospital discharge

Timepoint

One week after hospital discharge.

Method of measurement

Assessment of functional disability using the Quebec Functional Disability Scale questionnaire, which evaluates daily activity performance.

Intervention groups

1

Description

Intervention GroupIn: patients assigned to the intervention group, at the end of lumbar laminectomy surgery after complete completion of all surgical steps, achievement of adequate hemostasis and prior to final wound closure an erector spinae muscle block is performed using a direct surgical visualization technique. After gentle retraction of the superficial tissues and full exposure of the erector spinae muscles on both sides of the lumbar spine, the local anesthetic bupivacaine hydrochloride 0.25% equivalent to 2.5 mg/mL is injected into the deep fascial plane of the erector spinae muscle, adjacent to the transverse processes of the operated vertebrae. The injection volume is 20 mL on each side (total of 40 mL). The anesthetic is administered slowly

and incrementally, with prior aspiration performed to prevent inadvertent intravascular injection. The drug used is sterile injectable bupivacaine hydrochloride 0.25%, manufactured by Aspen Pharmaceutical Company, which is an approved product of the Food and Drug Administration of the Islamic Republic of Iran. The administered dose is selected within the established safe limits for local anesthesia, and the drug is administered only once at the end of surgery. The injection is performed by an experienced anesthesiologist, using a sterile single-use syringe and a standard needle. During the block procedure, the patient remains under stable general anesthesia, with standard monitoring in place, including non-invasive blood pressure, cardiac rhythm, oxygen saturation, and ventilation. No ultrasound guidance or additional imaging equipment is used for this intervention. All injection steps are performed within the surgical field, without creating any new skin puncture. This intervention is performed only once at the end of the surgery, and no repeat injections or additional interventional procedures are planned for the patient. Following completion of the injection and surgical wound closure, the patient enters the postoperative care phase, and further management including pain control and other supportive measures is carried out in accordance with standard institutional and ward protocols.

Category

Treatment - Drugs

2

Description

Control group: In this group, at the end of lumbar laminectomy surgery and after completion of the surgical procedure, an erector spinae muscle block is performed under direct surgical visualization; however, sterile normal saline is injected as a placebo instead of a local anesthetic. A volume of 20 milliliters on each side of the erector spinae muscle (total volume 40 milliliters) is administered. The injection is performed by an experienced anesthesiologist while the patient is under general anesthesia. All other anesthetic, surgical, and postoperative care are identical to the intervention group and follow a standardized protocol.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Meisam Ghorbanpoor

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Sponsors / Funding sources

1

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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

Babol 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

Babol University of Medical Sciences

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Shareable data comprise individual-level, de-identified participant data that will be provided after removal of all personal identifiers (name, national ID number, medical record number, contact information, and any direct or indirect identifiers). These data include baseline demographic characteristics, postoperative pain intensity, time to first intravenous analgesic requirement, length of hospital stay, and scores from the Quebec Functional Disability Scale. Raw data containing personal identifiers or medical record information will not be shared.
When the data will become available and for how long
Access to shared data will begin six months after publication of the final study results and will remain available for at least five years following the main publication.
To whom data/document is available

Access will be limited to researchers affiliated with academic institutions, research centers, or recognized scientific organizations with a relevant research background and clear institutional affiliation. Requests from individuals without formal scientific affiliation will not be considered.

Under which criteria data/document could be used

Data may be used only for non-commercial scientific research purposes, including secondary analyses, meta-analyses, and methodological studies. Commercial use, re-identification attempts, or redistribution without proper acknowledgment are prohibited. Conditions for access: 1- Submission of a brief research proposal 2- Signing a data-use and confidentiality agreement 3- Commitment to appropriate citation of the original study 4- Approval by the principal investigator

From where data/document is obtainable

Applicants should submit their request to the principal investigator of the study. Contact methods, in order of priority, include email communication with the principal investigator, official correspondence through Babol University of Medical Sciences, Faculty of Medicine, Department of Anesthesiology, and, if necessary, formal written communication via the university research office.

What processes are involved for a request to access data/document

Upon receipt of a formal request describing the intended use of the data, the request will be reviewed by the principal investigator. If approved, a data-use agreement will be issued. After the signed agreement is received, the de-identified dataset will be provided within 4 to 6 weeks.

Comments

The data-sharing program has been developed in accordance with research ethics principles, the approved ethics code and the clinical trial policies of the Islamic Republic of Iran. All decisions regarding data publication will be made on a case-by-case basis, with priority given to safeguarding the rights of participants.