Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison between the analgesic effects of the Erector Spinae Plane Block and direct Infiltration under the Erector Spinae muscles in degenerative lumbar vertebral surgeries

Protocol summary

Study aim
Comparison between the Analgesic Effects of the Erector Spinae Plane Block and Direct Infiltration Under the Erector Spinae muscles in Degenerative Lumbar vertebral Surgeries

Design
A randomized controlled clinical trial with parallel groups, double blinded

Settings and conduct
After approval by the ethics committee of Shahid Beheshti University of Medical Sciences and obtaining the consent of the patients, 64 patients aged between 20-70 years and ASA class I and II who are Degenerative Lumbar Vertebral Surgeries will be randomly assigned to 2 groups according to the table of random numbers.

Participants/Inclusion and exclusion criteria
Inclusion:ASA class I and II No history of psychiatric diseases No surgery or fracture in other body parts Exclusion: BMI over 30 Duration of surgery more than 3 hours

Intervention groups
Group 1: Degenerative Lumbar Vertebral Surgeries using ultrasound-guided erector spinae plane: A C60 curved array ultrasound probe (FUJIFILM SonoSite Edge II Total) with a frequency of 2-5 MHz is used, which is placed in the midline in the parasagittal. By in-plane method using a 20-Ga 4-inch needle, 20 milliliters of ropivacaine 0.25% will be injected bilaterally at the tips of the transverse process under visual guidance. Group 2: Degenerative Lumbar vertebral Surgeries using Direct Infiltration Under the Erector Spinae muscles: After the midline incision, the fascia is opened in the midline, then the muscles are dissected subperiosteally, and the muscle dissection continues from the transverse process to its lateral part. After laminectomy and screw insertion, at the end of the surgery, 20 cc of 0.25% rupivacaine solution is injected on each side of the device site.

Main outcome variables
intra-operative opioid consumption; Pain

General information

Reason for update

Acronym
ESPB

IRCT registration information
IRCT registration number: **IRCT20221107056427N1**
Registration date: **2022-11-23, 1401/09/02**
Registration timing: **retrospective**

Last update: **2022-11-23, 1401/09/02**
Update count: **0**

Registration date
2022-11-23, 1401/09/02

Registrant information

Name
Alireza Mirkheshti

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8833 4287

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison between the analgesic effects of the Erector Spinae Plane Block and direct Infiltration under the Erector Spinae muscles in degenerative lumbar vertebral surgeries

Public title
Determining the effectiveness of erector spinae block under ultrasound guidance in analgesia after lumbar vertebral surgeries
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for degenerative lumbar vertebral surgeries with a maximum of 4 screws in one or two adjacent vertebral levels. ASA class I and II No history of psychiatric diseases or drug and stimulant abuse No surgery or fracture in other body parts
Exclusion criteria:
History of previous lumbar vertebral surgeries BMI above 30 Duration of surgery more than 4 hours Bleeding rate more than 20% of body blood volume Surgery requiring the insertion of more than 4 screws or more than two adjacent lumbar vertebrae
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
A statistics consultant will perform randomization using permuted block technique. The permuted block technique randomizes patients between groups within a set of study participants, called a block. Treatment assignments within blocks are determined so that they are random in order but that the desired allocation proportions are achieved exactly within each block. The randomization sequences are delivered in sealed opaque envelopes to the anesthesiologist responsible for performing the blocks and induction of anesthesia.
Blinding (investigator's opinion)
Double blinded
Blinding description
Before the start of the study and at the time of patient admission, a full explanation is given in relation to the study, and an optional informed consent form is obtained from the patients to participate in the study. The randomization sequences will be delivered in sealed opaque envelopes to the anesthesiologist responsible for performing the blocks and induction of anesthesia. The principal investigator of the project, the medical personnel, the person in charge of data collection (anesthetist assistant), and the person who analyzes the data are also not aware of the grouping of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Yemen Street, Shahid Chamran Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-05-10, 1401/02/20
Ethics committee reference number
IR.SBMU.MSP.REC.1401.95

Health conditions studied

1

Description of health condition studied
Degenerative Lumbar vertebral Surgeries
ICD-10 code
S32.0
ICD-10 code description
Fracture of lumbar vertebra

Primary outcomes

1

Description
Postoperative analgesia
Timepoint
2, 6, 12 and 24 hours after the operation
Method of measurement
Patient file information

2

Description
morphine intake
Timepoint
2, 6, 12 and 24 hours after the operation
Method of measurement
Patient file information

Secondary outcomes

1

Description
Fentanyl used during surgery
Timepoint
during the surgery
Method of measurement
observation

Intervention groups

1

Description
Intervention group 1: Degenerative Lumbar vertebral Surgeries using Ultrasound-Guided Erector Spinae Plane Block: Bilateral ultrasound-guided ESPBs were performed with the patient in a prone position after induction of general anesthesia, prior to surgical incision. Blocks will be performed by experienced attending anesthesiologists, all of whom were fellowship-trained in regional anesthesia and were members of a dedicated spine anesthesia service. A C60 curved array ultrasound probe (FUJIFILM SonoSite Edge II Total) with 2-5 MHz was placed in parasagittal orientation in the midline to identify the spinous processes. The probe was translated laterally until the tips of the transverse processes were viewed. A 20-Ga 4-inch Ultraplex needle (B. Braun Medical Inc., PA, USA) was placed in-plane and advanced in a cranial-to-caudal direction until the tip was under the erector spinae plane. Depending on the patient's body mass index (BMI) 20 mL 0.25% rupivacaine was injected bilaterally at the tips of the transverse process/under visual guidance.
Category
Treatment - Surgery

2

Description
Intervention group 2: Degenerative Lumbar vertebral Surgeries using Direct Infiltration Under the Erector Spinae muscles: After the midline incision, the fascia is opened in the midline, then the muscles are dissected subperiosteally, and the muscle dissection continues from the transverse process to its lateral part. After laminectomy and screw insertion, at the end of the surgery, 20 cc of 0.25% rupivacaine solution is injected on each side on the device site.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Parisa Raji
Street address
The beginning of Shahid Madani Street, Imam Hossein Square
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Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehran, Iran
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Web page address
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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

Parisa Raji

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Position

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not 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