

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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% ropivacaine 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)

Phone

+98 21 8833 4287

Email address

amirkheshti@sbmu.ac.ir

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 Ultrplex 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% ropivacaine 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% ropivacaine 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

City

Tehran

Province

Tehran

Postal code

6314116177

Phone

+98 21 7343 3000

Email

Raji1389@gmail.com

Web page address

<https://ehmc.sbmu.ac.ir>

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

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9331

Email

zarghi@sbmu.ac.ir

Web page address

<https://remsp.sbmu.ac.ir/>

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

1617763141
Phone
+98 21 7343 3000
Email
raji1389@gmail.com
Web page address
<https://ehmc.sbmu.ac.ir>

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
Street address
Imam Hussein Medical, Educational, Research and
Medical Center, lower than Martyr Madani Metro,
Martyr Madani Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
Raji1389@gmail.com
Web page address
<https://ehmc.sbmu.ac.ir>

Person responsible for scientific 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
Street address
Imam Hussein Medical, Educational, Research and
Medical Center, lower than Martyr Madani Metro,
Martyr Madani Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code

Person responsible for updating data

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
Street address
Imam Hussein Medical, Educational, Research and
Medical Center, lower than Martyr Madani Metro,
Martyr Madani Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
Email
Raji1389@gmail.com
Web page address
<https://ehmc.sbmu.ac.ir>

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