

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparative assessment of the effectiveness of Erector Spina plane block with Thoracic Epidural anesthesia on postoperative pain of patients undergoing thoracic surgery.

Protocol summary

Study aim

Comparing the effectiveness of Erector Spina plane block to Thoracic Epidural anesthesia on postoperative analgesia in patients undergoing thoracic surgery

Design

A single blind, controlled clinical trial

Settings and conduct

76 patients aged 18 to 74, candidates for thoracic surgery, referred to Masih Daneshvari Hospital in Tehran, were divided into two groups of 38 by simple sequential randomization. Patient blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients aged 18 to 74, candidates for thoracic surgery. Exclusion criteria: patients with spinal deformity or history of addiction; coagulation disorder; Sensitivity to local anesthetic drugs and diseases related to nerve fibers.

Intervention groups

Intervention group: 38 patients will receive 20 ml of Bupivacaine 0.25% within erector spina plane block before surgery. For erector spina plane block one-sided single injection will be done deep in the erector spina muscle at the level of fifth thoracic vertebra Control group: 38 patients will receive 10 ml of Bupivacaine 0.25% via epidural catheter before surgery. The epidural catheter will be inserted before initiating surgery at the level of T6-T7.

Main outcome variables

Postoperative pain after thoracic surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230314057715N1**

Registration date: **2023-09-01, 1402/06/10**

Registration timing: **retrospective**

Last update: **2023-09-01, 1402/06/10**

Update count: **0**

Registration date

2023-09-01, 1402/06/10

Registrant information

Name

Jalil Sadeghi Bakhshmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2214 1399

Email address

jalilsadeghi824@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-18, 1402/03/28

Expected recruitment end date

2023-08-19, 1402/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of the effectiveness of Erector Spina plane block with Thoracic Epidural anesthesia on postoperative pain of patients undergoing thoracic surgery.

Public title
Effectiveness of Erector spina plane block, Effectiveness of Thoracic epidural anesthesia

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing thoracic surgery Age: 18 to 74 years
Exclusion criteria:
Patient dissatisfaction History of drug addiction History of allergy to local anesthetics History of coagulation disorders Critically ill patients, evidence of sepsis and patients who will require mechanical ventilation after surgery Patients with chest deformity Patients with neurological disorders and axonal diseases

Age
From **18 years** old to **74 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The person who will do the analysis will be blind to the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of School of Medicine-Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, School of medicine, Erabi street, Yaman street, Shahid Chamran highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1451744791

Approval date

2023-03-07, 1401/12/16

Ethics committee reference number

IR.SBMU.MSP.REC.1401.722

Health conditions studied

1

Description of health condition studied

Postoperative pain in thoracic surgery.

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Numerical score of pain after thoracic surgery

Timepoint

1 hour after surgery, 3 hours after surgery, 6 hours after surgery and 12 hours after surgery.

Method of measurement

Asking the patient based on the numerical pain score.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 38 patients will receive 20 ml of Bupivacaine 0.25% within erector spina plane block before surgery. For erector spina plane block one-sided single injection will be done deep in the erector spina muscle at the level of fifth thoracic vertebra.

Category

Treatment - Other

2

Description

Control group: 38 patients will receive 10 ml of Bupivacaine 0.25% via epidural catheter before surgery. The epidural catheter will be inserted before initiating surgery at the level of T6-T7.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital
Full name of responsible person
 Tahereh Parsa
Street address
 Darabad ,Nyavaran
City
 Tehran
Province
 Tehran
Postal code
 1956944413
Phone
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Fax
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Email
 pr.nritld@sbmu.ac.ir
Web page address
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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
 5th floor, Building number 2, Shahid Beheshti
 university of medical sciences, Erabi street, Yaman
 Street, Shahid Chamran highway
City
 Tehran
Province
 Tehran
Postal code
 193954631
Phone
 +98 21 2243 9780
Fax
 +98 21 2243 9780
Email
 info@sbmu.ac.ir
Web page address
 https://research.sbm.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

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Jalil Sadeghi Bakhshmand

Position

Resident of anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Parsa

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Jalil Sadeghi Bakhshmand

Position

Resident of anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

Upon request by correspondence via email or phone call.

When the data will become available and for how long

6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

To conduct relevant research and meta-analysis.

From where data/document is obtainable

National Research Institute of Tuberculosis and Lung Diseases

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

Correspondence via e-mail with the person in charge of the project, Dr. Tahereh Parsa.

Comments