

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  
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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  
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**Email**  
info@sbmu.ac.ir  
**Web page address**  
<https://research.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

## 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  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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Tahereh Parsa  
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Associate professor  
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Subspecialist  
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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

**Street address**

Darabad, Nyavaran

**City**

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1956944413

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**Email**

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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**