Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Medicin-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
+98 21 2610 5050

Fax
+98 21 2610 9490

Email
pr.nritld@sbmu.ac.ir

Web page address
https://nritld.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
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.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

Street address
Darabad Nyavaran

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Fax
+98 21 2610 9490

Email
jalilsadeghi824@yahoo.com

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

Street address
Darabad, nyavaran

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
tparsa849@sbmu.ac.ir

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
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Province
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jalilsadeghi824@yahoo.com

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