Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison of analgesic effect of erector spinae plane block versus intercostal nerve blck in VATS surgery under general anesthesia without opioid

Protocol summary

Study aim

Comparison of analgesia in the erector spinae method and intercostal block on pain intensity and opioid consumption in patients undergoing VATS surgery with general anesthesia without narcotics

Design

This study is a randomized clinical trial with parallel intervention groups and no placebo. Assessment of pain severity and opioid consumption is performed by a blinded evaluator, and patients are unaware of the type of block received

Settings and conduct

This study will be conducted at Masih Daneshvari Hospital, Tehran. After obtaining informed consent from eligible patients VATS surgery will be performed without general anesthesia. Patients will be randomly divided into two groups: erector spinae block and intercostal block Both groups will be performed under ultrasound guidance by an experienced anesthesiologist. Data on pain intensity and other outcomes will be reviewed 2, 6, 12, and 24 hours after surgery

Participants/Inclusion and exclusion criteria

Patients aged 18 to 70 years with a general status of ASA 1-3, candidates for VATS surgery under general anesthesia without narcotics and informed consent will be eligible for inclusion. Patients with coagulation disorders, infection at the site of the pregnancy block injection, sensitivity to the anesthetic, history of addiction, multiple trauma, inability to cooperate in pain assessment will be excluded from the study

Intervention groups

This study includes two groups: 1- Erector spinae block, in which 20 ml of 0.25% bupivacaine is injected at the T5 level under ultrasound guidance. Group 2- Intercostal block, in which a total of 15 cc of 0.25% bupivacaine is injected in three spaces adjacent to the incision site

Main outcome variables

Postoperative pain intensity will be measured using a visual analog scale (VAS) at 2 6 12 and 24 hours after the end of surgery

General information

Reason for update

Acronym

EVAT(erctor vs intercostal block in VATS analgesia trial)

IRCT registration information

IRCT registration number: **IRCT20250929067410N1**
Registration date: **2026-02-08, 1404/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-08, 1404/11/19**
Update count: **0**

Registration date

2026-02-08, 1404/11/19

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-26, 1404/10/05

Expected recruitment end date

2026-02-24, 1404/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of analgesic effect of erector spinae plane block versus intercostal nerve blck in VATS surgery under general anesthesia without opioid

Public title

comparison of analgesic effect of erector spinae plane block versus intercostal nerve blck in VATS surgery under general anesthesia without opioid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- age between 18 and 70 years 2- scheduled for video - assisted thoracoscopic surgery under general anesthesia with out opioid administration.3- asa physical status 1-3 4- ability to provide witten informed consent 5- no known allergy to syudy drug (local anesthesia such as bupivacaine or ropivacaine)

Exclusion criteria:

1- Unwillingness to participate in the study or withdrawal at any stage 2- History of major thoracic surgery or anatomical changes that prevent proper block implementation 3- Infection at the block injection site 4- Severe cardiac, pulmonary, or renal disease that increases the risk of anesthesia 5- Coagulation disorders or use of active anticoagulant drugs 6- Pregnancy or breastfeeding 7- Inability to assess pain

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **1**

Test power: 0.8 *Alpha: 0.05 *Total difference in 1: vas unit *Standard deviation: 2 units *Ratio between treatment and control group: 1:1 * Considering data loss: 25 people in each group, therefore, the total size: 50 people

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient, after entering and confirming the inclusion criteria, is placed in one of two study groups: Group A: Erector Spina Plate Block (ESPB) Group B: Intercostal Block (ICB) The anesthesiologist is aware of the group assignment before the block is performed, but the patient and the pain assessor are unaware of the treatment group. This method prevents BIAS in the assessment (pain severity). If an eligible patient withdraws after allocation or the procedure is canceled, a replacement sample will be selected from the next random numerical block to keep the number of samples in the two groups equal.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, double-blinding is used. The patient and the pain assessor are unaware of the type of block. Only the anesthesiologist performing the block is aware of the type of intervention. The patient is under general anesthesia and remains unaware of the intervention. The pain assessor who measures the VAS score after surgery and the data analyst are not aware of the patients' treatment group. After collecting the data, they are entered into the statistical software with A-B codes and decoding is performed after the analysis is complete. This design prevents observer and patient bias in assessing the outcomes after pain and medication use

Placebo

Not used

Assignment

Parallel

Other design features

This study is a randomized clinical trial with parallel groups. After obtaining informed consent, eligible patients will be randomly assigned to two groups: Group A, receiving the erector spinae plate block, and Group B, receiving the intercostal block. The randomization method is based on four-blocks with an allocation ratio of 1:1. Pain intensity is assessed at intervals of 2, 6, 12, and 24 hours after surgery using the VAS scale. Patients and pain assessors are unaware of the assigned group. (Double-blind) Data will be analyzed using appropriate statistical tests including independent t-test and repeated analysis of variance.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran, Shahid Bahonar Street (Niavaran), Darabad

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2025-10-12, 1404/07/20

Ethics committee reference number

ir.sbmu.retech.rec.1404.539

Health conditions studied

1

Description of health condition studied
Patients who are candidates for video-assisted thoracoscopic surgery under general anesthesia without narcotics. This procedure is usually performed in patients with various lung diseases such as lung masses, pleural effusions, or lung biopsies

ICD-10 code
j90 c34.9

ICD-10 code description
Lung mass, pleural effusion, or lung biopsy condidates undergoing vats surgery

Primary outcomes

1

Description
Postoperative pain intensity at 2, 6, 12, and 24 hours after surgery based on the visual analog scale (VAS)

Timepoint
At 2, 6, 12, 24 hours after surgery

Method of measurement
Using a visual analogue scale (VAS) of pain by a pain assessor who is unaware of the patient grouping

2

Description
Changes in vital signs (blood pressure, heart rate, oxygen saturation) in the hours after surgery

Timepoint
Measurement by pain assessor at 2, 6, 12, and 24 hours after surgery

Method of measurement
% -mmhg-bpm

3

Description
Possible complications with the block, such as hematoma, pneumothorax, and hypotension

Timepoint
Clinical assessment and recording during the 24 hours after surgery

Method of measurement
Incidence percentage

Secondary outcomes

1

Description
Amount of pain medication used within 24 hours after surgery

Timepoint
Record the total amount of painkillers prescribed, such as diclofenac, acetaminophen, or other narcotics, in the patient's record within 24 hours after surgery

Method of measurement
Units based on milligrams, for example 2 mg of morphine intravenously three hours after surgery

Intervention groups

1

Description
Intervention group: Intervention group: Group A: Erector spinae plate block in the lateral position after general anesthesia without narcotics and prep and drape, performed with ultrasound guidance, 20 cc of 0.25% marcaine solution is injected at the T5 level in the space between the fascia and the erector spinae muscle. The intervention is performed by an experienced anesthesiologist in this field. Number of times: once for each patient

Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: Intercostal block group, in which after general anesthesia, after positioning and before the start of surgery, 5 cc of 0.25% marcaine solution will be injected into each of the three intercostal spaces at the surgical incision site under ultrasound guidance. The total injection will be 15 cc. The intervention will be performed by an experienced anesthesiologist. The number of times is once for each patient

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari Hospital

Full name of responsible person
Lida Fadaizadeh / Tahereh Parsa

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dr. Masih Daneshvari Educational, Research and Treatment Center
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
Lida Fadaizadeh / Tahera Parsa
Position
Professor,
Latest degree
Subspecialist
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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data from this study, including results on pain intensity, analgesic use, and possible complications of the regional block, will be provided to the research team confidentially after the final analysis is completed. The data will be coded and only the mean and standard deviation will be published in the final report

When the data will become available and for how long
The data will be available after the final article is completed and published. This period is estimated to be approximately 6 to 12 months after the end of data collection

To whom data/document is available
The data will only be available to the project implementation group, and limited and confidential access will be provided to other researchers upon written request and approval by the ethics committee

Under which criteria data/document could be used
The data includes pain intensity, opioid consumption, and potential side effects of the regional block technique. The data will be coded after analysis and will be used for research and educational purposes only

From where data/document is obtainable
The request will be given to the principal investigator, and coordination and authorization will be done with the supervisor and the medical ethics committee

What processes are involved for a request to access data/document
Applicants must submit their request in writing to the principal investigator, and after approval by the supervisor and the ethics committee, it will be submitted in an encrypted format and in accordance with the principle of confidentiality

Comments
No identifying information will be included in the shareable files, and the documents will be stored on the Masih Daneshvari research server. Only the data will appear in the final article as results