

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of Extrapleural Paravertebral Block Versus Thoracic Epidural Block For Post-Thoracotomy Pain

Protocol summary

Study aim

To compare the clinical outcomes and analgesic efficacy in patient's post-thoracotomy treated with extra pleural paravertebral block (PVB) versus thoracic epidural anesthesia (TEA)

Design

A prospective, two-arm, parallel-group, non-randomized clinical trial comparing extra pleural paravertebral block and thoracic epidural block for post-thoracotomy pain. Participants will be allocated to either group without randomization. No blinding will be performed. sample size 140 Participants.

Settings and conduct

This quasi-experimental study was carried out at the Department of Anesthesiology, Combined Military Hospital, Rawalpindi from Jan-Jun 2024.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: ASA-II and III male and female patients between ages 25-65 years presenting in the pre-anesthesia clinic planned for an elective diagnostic and/or therapeutic thoracotomy. Exclusion Criteria: Patients with metastatic disease, major cardiac or respiratory disease, low ejection fraction, post chemotherapy, allergy to lignocaine and/or bupivacaine, unwilling to be included in the study, infection at site of block, coagulation disorders, ineffective regional block, and failure to perform block after three consecutive attempts by a consultant pain specialist

Intervention groups

The patients were divided into Group A (n=70) to receive Paravertebral block (PVB) and Group B (n=70) to receive thoracic epidural anesthesia (TEA)

Main outcome variables

Primary variables studied were median Visual Analogue Scale Score for first 24 hours after 6 hour intervals and mean dose of added rescue analgesia (Intravenous Nalbuphine 0.15 mg/kg) required once pain scores reached above 5 on the Visual Analogue Scal scale for all patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260718070247N1**

Registration date: **2026-08-02, 1405/05/11**

Registration timing: **retrospective**

Last update: **2026-08-02, 1405/05/11**

Update count: **0**

Registration date

2026-08-02, 1405/05/11

Registrant information

Name

Muhammad Tayyab

Name of organization / entity

Combined Military Hospital Rawalpindi

Country

Pakistan

Phone

+92 51 9273426

Email address

capt.tayyab10025@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-01, 1402/10/11

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

2024-01-01, 1402/10/11

Actual recruitment end date

2024-06-30, 1403/04/10

Trial completion date

empty

Scientific title

Comparison of Extraplural Paravertebral Block Versus Thoracic Epidural Block For Post-Thoracotomy Pain

Public title

Comparison of Extraplural Paravertebral Block Versus Thoracic Epidural Block For Post-Thoracotomy Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

ASA-II and III Male and Female Ages 25-65 years Patients presenting in the pre-anesthesia clinic planned for an elective diagnostic and/or therapeutic thoracotomy.

Exclusion criteria:

Metastatic disease, Major cardiac or respiratory disease Post chemotherapy, Allergy to lignocaine and/or bupivacaine Unwilling to be included in the study Infection at site of block Coagulation disorders, Ineffective regional block Failure to perform block after three consecutive attempts by a consultant pain specialist

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **140**

More than 1 sample in each individual

Number of samples in each individual: **70**

Actual sample size reached: **140**

More than 1 sample in each individual

Actual sample size in each individual: **70**

The patients were divided into Group A (n=70) to receive Paravertebral block (PVB) and Group B (n=70) to receive thoracic epidural anesthesia (TEA)

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Approval date

empty

Ethics committee reference number

2

Ethics committee

Approval date

empty

Ethics committee reference number

3

Ethics committee

Name of ethics committee

Ethical Review Committee/ Institutional Review Board, Combined Military Hospital Rawalpindi

Street address

Combined Military Hospital Rawalpindi (CMH), CMH Rd, Rawalpindi, 46000

City

Rawalpindi

Postal code

46000

Approval date

2025-09-11, 1404/06/20

Ethics committee reference number

719

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Acute post-thoractomy pain

ICD-10 code

G89.12

ICD-10 code description

Acute post-thoracotomy pain

Primary outcomes

1

Description

Pain

Timepoint

01, 06, 12,18, 24 Hours

Method of measurement

Visual Analogue Scale Score

Secondary outcomes

1

Description

Frequency of Hypotension

Timepoint

In 24 hours.

Method of measurement

Non-invasive blood pressure measurement via sphygmomanometer

2**Description**

Frequency of bradycardia

Timepoint

In 24 hours

Method of measurement

Pulse oximeter

3**Description**

Frequency of nausea/vomiting

Timepoint

In 24 hours

Method of measurement

Observation

4**Description**

Frequency of respiratory depression

Timepoint

In 24 hours

Method of measurement

Respiratory rate

5**Description**

Patient satisfaction

Timepoint

After 24 hours

Method of measurement

Likert Scale

Intervention groups**1****Description**

Group A (n=70): Patients will receive an extrapleural paravertebral block (EPVB) for postoperative analgesia after thoracotomy according to the institutional protocol.

Category

Other

2**Description**

Group B (n=70): Patients will receive thoracic epidural analgesia (TEA) for postoperative analgesia after thoracotomy according to the institutional protocol.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Combined Military Hospital Rawalpindi, Pakistan

Full name of responsible person

Muhammad Tayyab

Street address

Combined Military Hospital Rawalpindi (CMH), CMH Rd, Rawalpindi, 46000

City

Rawalpindi

Postal code

46000

Phone

+92 51 9273426

Email

rabnawaz.bangash3061@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Combined Military Hospital Rawalpindi

Full name of responsible person

Muhammad Tayyab

Street address

Combined Military Hospital Rawalpindi (CMH), CMH Rd, Rawalpindi, 46000

City

Rawalpindi

Postal code

46000

Phone

+92 51 9273426

Email

rabnawaz.fcm@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Combined Military Hospital Rawalpindi

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

Combined Military Hospital Rawalpindi

Full name of responsible person

Muhammad Tayyab

Position

Graded Specialist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Combined Military Hospital Rawalpindi (CMH), CMH
Rd, Rawalpindi, 46000

City

Rawalpindi

Province

Punjab

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46000

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Email

rabnawaz.bangash3061@gmail.com

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rabnawaz.bangash3061@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Combined Military Hospital Rawalpindi

Full name of responsible person

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Email

rabnawaz.bangash3061@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Combined Military Hospital Rawalpindi

Full name of responsible person

Muhammad Tayyab

Position

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Latest degree

Specialist

Other areas of specialty/work

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not 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

No - There is not a plan to make this available