

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison of Extraplural 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

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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**

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**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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Combined Military Hospital Rawalpindi

**Full name of responsible person**

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Specialist

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## Person responsible for scientific 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**

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46000

**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