

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of thoracic epidural block versus erector spinae plane block for post operative pain relief in thoracotomies

#### Protocol summary

##### Study aim

The main aim of this study is to compare the post-operative analgesic efficacy of thoracic epidural block when compared with erector spinae plane block in patients post-thoracotomies

##### Design

Randomized controlled trial. Method of randomization was non-probability consecutive by lottery method.

##### Settings and conduct

Patients were randomized into two groups thoracic epidural block (Group T) and erector spinae group (Group E) an informed written consent was taken. Standard monitoring was attached in both groups. After securing IV line and preparing patient patient in Group T were placed in sitting position and 18G tuohy needle was passed for catheter in T3-6 epidural space. In Erector Spinae Group patient were placed in semi lateral position and block was performed as per NYSORA guidelines and 20G catheter placed in situ for infusion in next 24 person ours.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria included all male and female patients between ages 25-75 years presenting in the operating room for elective thoracotomies. Exclusion Criteria included patients with metastatic disease, major cardiac or respiratory disease, low ejection fraction, post chemotherapy, allergy to lignocaine or bupivacaine, patients with advanced polytrauma causing hemodynamic instability, patients with oxygen saturation less than 92 percent after supplemental oxygen or patients unwilling to be included in the trial.

##### Intervention groups

Patients were divided into two interventional groups thoracic epidural block group (Group T) (n=20) and erector spinae block group (Group E) (n=20).

##### Main outcome variables

Mean time to first dose analgesia Total dose of intravenous analgesia needed in 24 hours Median pain scores at 1,3,6,12 and 24 hours Patient satisfaction

Score for pain relief in 24 hours

#### General information

##### Reason for update

##### Acronym

ESP (Erector Spinae Block)

##### IRCT registration information

IRCT registration number: **IRCT20231113060036N1**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

##### Registration date

2024-02-07, 1402/11/18

##### Registrant information

##### Name

Sikander Hayat

##### Name of organization / entity

National university of medical sciences rawalpindi

##### Country

Pakistan

##### Phone

+92 346 6582936

##### Email address

sikanderhayat94@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-01, 1402/04/10

##### Expected recruitment end date

2024-02-10, 1402/11/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of thoracic epidural block versus erector spinae plane block for post operative pain relief in thoracotomies

**Public title**  
Comparison of Thoracic Epidural Block versus Erector Spinae Plane Block for post operative pain relief in thoracotomies

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All male and Female patients between ages 25-75 years Presenting in operating room for thoracotomies  
**Exclusion criteria:**  
Patients with metastatic disease Major cardiac or respiratory disease Low ejection fraction Post chemotherapy Allergy to lignocaine or bupivacaine Patients with advanced polytrauma causing haemodynamic instability Patients with oxygen saturation less than 92 percent Patients unwilling to be included in trial

**Age**  
From **25 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **55**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The method of randomization was non probability consecutive by lottery method

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
N/A

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**  
**Name of ethics committee**

Ethical Committee of Combined Military Hospital Rawalpindi

**Street address**  
CMH Road Rawalpindi

**City**  
Rawalpindi

**Postal code**  
46000

**Approval date**  
2023-07-01, 1402/04/10

**Ethics committee reference number**  
494

## Health conditions studied

1

### Description of health condition studied

Comparison of Pain relief in patients with thoractimies post operatively using erector spinae and epidural block

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

Median pain scores, Mean time to first rescue analgesia, total dose of intravenous analgesia needed in 24 hours, patient satisfaction for pain relief

### Timepoint

Median pain scores at 1, 3,6, 12 and 24 hours, total intravenous analgesia needed in 24 hours after intervention, patient satisfaction score 24 hours after intervention

### Method of measurement

Visual analogue Score, patient satisfaction score on a 7 point likert scale. Total dose of analgesia in milligram

## Secondary outcomes

1

### Description

Nausea/Vomiting, hypotension and sedation

### Timepoint

24 hours after intervention

### Method of measurement

Number of episodes of vomiting,Manometry, GCS

## Intervention groups

1

### Description

Intervention group:

### Category

Treatment - Other

**2**

**Description**

Intervention group:

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Combined Military Hospital Rawalpindi Punjab  
Pakistan

**Full name of responsible person**

Sikander Hayat

**Street address**

House No. 6054/18-B Rose lane 09 New Lalazaar

**City**

Rawalpindi

**Postal code**

46600

**Phone**

+92 346 6582936

**Email**

Sikanderhayat94@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Combined Military Hospital Rawalpindi

**Full name of responsible person**

Kamran Ahmed

**Street address**

CMH Road Rawalpindi

**City**

Rawalpindi

**Postal code**

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**Phone**

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kahmed72462@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**

National University of Medical Sciences

**Full name of responsible person**

Ali Raza

**Position**

Registrar

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

National University of Medical Sciences Rawalpindi

**Full name of responsible person**

Atta Amin

**Position**

Registrar

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

National university of Medical Sciences

**Full name of responsible person**

Sikander Hayat

**Position**

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Medical doctor

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## 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**

Undecided - It is not yet known if there will be 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**

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