

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 patoent 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

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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 satifaction 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined Military Hospital Rawalpindi

Full name of responsible person

Kamran Ahmed

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CMH Road Rawalpindi

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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

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

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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

Registrar

Latest degree

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