

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### COMPARISON OF PARAVERTEBRAL BLOCK (PVB) VERSUS EPIDURAL ANESTHESIA IN PARTIAL PNEUMONECTOMY FOR BRONCHIECTASIS IN THE GERIATRIC AGE GROUP

#### Protocol summary

##### Study aim

The aim of this study is to compare the per and post-operative analgesic efficacy and adverse effect profile of ultrasound guided paravertebral plane block versus epidural anesthesia in patients with bronchiectasis planned for partial pneumonectomy.

##### Design

Parallel group, single center, interventional randomized controlled trial

##### Settings and conduct

Done at Combined Military Hospital, Rawalpindi

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included all ASA-II and III patients between ages 60-70 years presenting in the thoracic surgical department for partial pneumectomy for bronchiectasis. Exclusion criteria included patients with major cardiac or respiratory disease, low ejection fraction, allergy to bupivacaine or nalbuphine, unwilling to be included in the study, infection at site of block, coagulation disorders or spine deformity or having contraindication to epidural insertion.

##### Intervention groups

The patients will be divided into the paravertebral group (PVB) (n=45) and epidural group (n=45). The method of sampling was non-probability consecutive sampling via lottery method. Patients in the paravertebral group (PVB) were taken to the procedure room before starting the procedure. Paravertebral block was given in sitting position with the arms of the patient extended. Confirmation correct needle placement was done by deflection of the pleura downwards on injecting 2 mL of saline. Patient in the epidural group were prepped for procedure and 18 G epidural catheter after priming was inserted in the T8 vertebral space.

##### Main outcome variables

Primary variables measured were per-operative analgesia requirement, patient satisfaction for pain relief

24 hours after surgery and 24- hour total dose of analgesia needed. Secondary variables observed were hypotension, nausea, shivering and respiratory depression.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230812059125N1**

Registration date: **2023-08-22, 1402/05/31**

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

Last update: **2023-08-22, 1402/05/31**

Update count: **0**

##### Registration date

2023-08-22, 1402/05/31

##### Registrant information

##### Name

Saad Hameed

##### Name of organization / entity

Combined Military Hospital (CMH) Rawalpindi

##### Country

Pakistan

##### Phone

+92 943 412591

##### Email address

saadhameed\_bhattachi@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-01, 1402/05/10

##### Expected recruitment end date

2023-11-01, 1402/08/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

COMPARISON OF PARAVERTEBRAL BLOCK (PVB) VERSUS EPIDURAL ANESTHESIA IN PARTIAL PNEUMONECTOMY FOR BRONCHIECTASIS IN THE GERIATRIC AGE GROUP

**Public title**

PVB VERSUS EPIDURAL FOR PAIN RELIEF IN PNEUMECTOMY PATIENTS

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Included all ASA-II and III patients between ages 60-70 years presenting in the thoracic surgical department for partial pneumectomy for bronchiectasis

**Exclusion criteria:**

Major cardiac or respiratory disease Low ejection fraction Infection at block site Coagulation disorders Allergic to bupivacaine or nalbuphine Unwilling to be included in the study

**Age**

From **60 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **106**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomized into the PVB group and the Epidural group by non-probability consecutive sampling by lottery method

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

Name of ethics committee

Ethical review board CMH Rawalpindi

**Street address**

CMH Rawalpindi

**City**

Rawalpindi

**Postal code**

46000

**Approval date**

2023-01-01, 1401/10/11

**Ethics committee reference number**

ERB#267

**Health conditions studied****1****Description of health condition studied**

Analgesic efficacy of regional block in geriatric patients with bronchiectasis

**ICD-10 code**

J47

**ICD-10 code description**

Bronchiectasis

**Primary outcomes****1****Description**

Primary variables measured were per-operative analgesia requirement, patient satisfaction for pain relief 24 hours after surgery and 24- hour total dose of analgesia needed after the block

**Timepoint**

Pain relief and total analgesia needed after the block intervention for 24 hours

**Method of measurement**

Total dose of analgesia needed by adding doses from the proforma and pain score by the standard visual analog scale

**Secondary outcomes****1****Description**

Secondary variables observed were hypotension, nausea, shivering and respiratory depression.

**Timepoint**

For 24 hours after block administration

**Method of measurement**

Frequency of symptoms as noted by the resident anesthetist on duty in the high dependency unit

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

Intervention group 1: Paravertebral block block group (PVB)

**Category**  
Treatment - Other

2

**Description**  
Intervention group 2: Epidural anesthesia group  
**Category**  
Treatment - Other

## Recruitment centers

1

**Recruitment center**  
**Name of recruitment center**  
Combined Military Hospital (CMH) Rawalpindi  
**Full name of responsible person**  
Dr. Saad Hameed  
**Street address**  
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**City**  
Rawalpindi  
**Postal code**  
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**Phone**  
+92 321 5420669  
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saadhameed\_bhatti@hotmail.com

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**  
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Dr. Saad Hameed Bhatti  
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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**  
CMH Rwp  
**Proportion provided by this source**  
1  
**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**  
Persons

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Combined Military Hospital (CMH) Rawalpindi  
**Full name of responsible person**  
Saad Hameed  
**Position**  
Consultant  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for scientific inquiries

**Contact**  
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**Position**  
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## Person responsible for updating data

### Contact

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Combined Military Hospital (CMH) Rawalpindi

**Full name of responsible person**

Saad Hameed

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Original manuscript along with complete study data set and SPSS output sheets

**When the data will become available and for how long**

After approval of the manuscript for publication by a journal

**To whom data/document is available**

All medical academics including students and consultants

**Under which criteria data/document could be used**

Can be used as reference for academic purposes after permission of original author

**From where data/document is obtainable**

Will be shared online through cloud sharing after approval by author

**What processes are involved for a request to access data/document**

Formal email to the author requesting permission and how it would be used

**Comments**