

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 stadard 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

CMH Rwp

City

Rawalpindi

Postal code

46000

Phone

+92 321 5420669

Email

saadhameed_bhatti@hotmail.com

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

CMH Rwp

Full name of responsible person

Dr. Saad Hameed Bhatti

Street address

CMH Rwp

City

Rawalpindi

Postal code

46000

Phone

+92 321 5420669

Email

saadhameed_bhatti@hotmail.com

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

Street address

OT complex CMH Rawalpindi

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 943 412591

Fax**Email**

saadhameed_bhatti@hotmail.com

Person responsible for scientific 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

Street address

OT complex CMH Rawalpindi

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 943 412591

Fax**Email**

saadhameed_bhatti@hotmail.com

Person responsible for updating data

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

Street address

OT complex CMH Rawalpindi

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 943 412591

Fax**Email**

saadhameed_bhatti@hotmail.com

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