Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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 mauscript along with complete study data set and SPSS output sheets

When the data will become available and for how long
After approval of the mauscript 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