ISRCTN16782271 https://doi.org/10.1186/ISRCTN16782271

Comparing two pain relief methods for lung surgery: where anesthetic is injected near the spine (erector spinae plane block) versus near the spinal nerves (thoracic paravertebral block)

Submission date
20/12/2024

Registration date
25/12/2024

Last Edited
12/05/2025

Recruitment status
No longer recruiting

Overall study status
Ongoing

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study aims to compare two analgesic techniques in lobectomy surgery. The goal is to identify the most effective analgesic method to minimize the need for morphine, thereby enhancing the quality of recovery. The two methods being compared are the continuous Erector Spinae Plane Block (ESPB) and the Thoracic Paravertebral Block (TPVB).

Who can participate?
Patients undergoing lobectomy aged over 18 years old

What does the study Involve?
- Preoperatively: Patients are randomly assigned to either the ESPB or TPVB group using permuted block randomization in R. A 15 mL bolus of 0.5% ropivacaine is administered 10-15 minutes before the surgical incision.
- Intraoperatively: Patients receive a 1 mcg/kg dose of fentanyl intravenously for pain management.
- Postoperatively: In the PACU, patients are given a 15 mL autobolus of 0.2% ropivacaine every 6 hours via an infusion pump. Baseline analgesia includes IV paracetamol (1 g every 6 hours), IV ketorolac (every 8 hours), or nefopam (20 mg every 8 hours). Pain is further managed with titrated doses of IV morphine (1-2 mg as needed every 10 minutes).

What are the possible benefits and risks of participating?
- Benefits: Participants will have access to one of two advanced regional anesthesia techniques expected to effectively manage pain in lobectomy surgery. This can facilitate early postoperative recovery and reduce reliance on opioids, minimizing their potential adverse effects. Additionally, participants will contribute to research that seeks to refine pain management protocols, potentially enhancing future treatments for the broader community.
- Risks: Although the primary goal is to optimize postoperative analgesia, there is a small risk of complications associated with the anesthesia techniques used. These complications can include

local anesthetic toxicity, pleural puncture, vascular puncture, and potential allergic reactions or anaphylaxis. These complications are rare, and the study includes comprehensive protocols to manage any adverse effects. Medical staff will closely monitor participants to address potential complications promptly.

Where is the study Run From?
University Medical Center HCMC, University of Medicine and Pharmacy at Ho Chi Minh City (Vietnam)

When is the study starting and how long is it expected to run for?
July 2024 to September 2025

Who is funding the Study?
University Medical Center HCMC, University of Medicine and Pharmacy at Ho Chi Minh City (Vietnam)

Who is the main Contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparison of analgesic efficacy between erector spinae plane block and thoracic paravertebral block in lobectomy surgery

Study objectives
Analgesic efficacy of continuous erector spinae plane block is non-inferior to continuous thoracic paravertebral block

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/10/2024, Ethics council in biomedical research, University of Medicine and Pharmacy (217 Hong Bang, Ward 11, District 5, Ho Chi Minh, 700000, Viet Nam; +84 28 3855 0507; hoidongdaoducdhyd@ump.edu.vn), ref: IRB-VN01002/IRB00010293/FWA00023448

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Analgesics and quality of recovery in thoracic surgery

Interventions
A. Pre-operative Stage:
- Quality of Recovery (QoR-15) Assessment: Patients will undergo a baseline evaluation using the QoR-15 questionnaire to assess the quality of recovery.
- Randomization and Group Allocation: Patients will be randomly assigned into two groups using permuted block randomization executed with the sample function in R. The two groups are the ESPB group (Erector Spinae Plane Block) and the TPVB group (Thoracic Paravertebral Block).
- Anesthesia and Preparation: All participants will receive general anesthesia via double-lumen

endobronchial tubes. Each patient will then be prepared for either an ESPB or TPVB at the T5 vertebral level, where a catheter will be placed. A bolus of 15 mL of 0.5% ropivacaine will be administered 10-15 minutes before the surgical incision.

B. Intra-operative Stage:
- Monitoring and Analgesia Adjustments: Should a patient's heart rate or mean arterial pressure rise more than 30% above the baseline, a dose of 1 mcg/kg fentanyl will be administered intravenously.
- Wound Closure and Additional Medication: Just before skin closure, each patient will receive intravenous paracetamol (1 g), ketorolac (30 mg), or nefopam (20 mg IV).
- Extubation: Patients will be extubated after surgery, and the time of surgical completion will be documented.

C. Post-operative Stage:
- Pain Management in PACU: Patients will be monitored in the Post-Anesthesia Care Unit (PACU). An intermittent autobolus of 15 mL of 0.2% ropivacaine will be administered every 6 hours via an automated infusion pump through either the spinal or erector spinae plane catheter.
- Sensory Block Assessment: The level of the sensory block will be evaluated at 6 and 24 hours postoperatively to assess the effectiveness of the block.
- Morphine Titration and Pain Assessment: The total morphine consumption will be recorded. Pain will be measured using the Visual Analog Scale (VAS) at rest and during coughing at 1, 2, 6, 12, 24, 48, and 72 hours post-operatively. If VAS is ≥ 4, titrated doses of morphine (1-2 mg IV) will be administered every 10 minutes until VAS is < 4. Titration will be discontinued if VAS < 4, respiratory rate falls below 10 breaths per minute, or in cases of excessive sedation.
- Baseline Pain Management: Ongoing analgesia will include intravenous paracetamol (1 g every 6 hours) and slow IV ketorolac (every 8 hours), or alternatively nefopam (20 mg IV every 8 hours).
- Follow-up QoR-15 Assessment: Patients will be reassessed using the QoR-15 at 24 and 48 hours post-operatively to evaluate the recovery quality.

Intervention Type
Procedure/Surgery

Primary outcome measure
Total morphine consumption within 24 and 48 hours post-operatively measured using data collected from medical records at one timepoint

Secondary outcome measures
1. Total fentanyl consumption intra-operatively measured using data collected from medical records at one timepoint
2. Pain scores measured using the Visual Analog Scale (VAS) at rest and during cough at time points 1, 2, 6, 12, 24, 48, and 72 hours post-operatively
3. The level of dermatomal blockade and complications associated with the block techniques measured using data collected from medical records at one timepoint
4. Opioid-related side effects measured using data collected from medical records at one timepoint
5. Quality of recovery measured using the QoR-15 scale at baseline and 24 and 48 hours post-operatively

Overall study start date
01/07/2024

Completion date
30/12/2025

Eligibility

Key inclusion criteria
1. Patients scheduled for lobectomy
2. Agreed to participate in the study
3. No contraindications for ESPB and TPVB and the drugs used in the study
4. Physical status according to the American Society of Anesthesiologists (ASA) from I to III

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
40

Total final enrolment
34

Key exclusion criteria
1. Invasive mechanical ventilation postoperatively
2. Reoperation within 48 hours after surgery
3. Chronic pain or opioid use for over 3 months

Date of first enrolment
20/01/2025

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Viet Nam

Study participating centre
University Medical Center HCMC
215 Hong Bang, Ward 11, District 5
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Sponsor information

Organisation
University Medical Center HCMC

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University of Medicine and Pharmacy in Ho Chi Minh City
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Sponsor type
Hospital/treatment centre

Website
https://www.bvdaihoc.com.vn/

ROR
https://ror.org/0154qvp54

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center HCMC, University of Medicine and Pharmacy in Ho Chi Minh City

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal

Intention to publish date
30/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author upon reasonable request, Ha Quoc Hung M.D., haquochungmd@gmail.com or dao.ntn@umc.edu.vn

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			24/12/2024	No	Yes
Basic results		07/05/2025	07/05/2025	No	No
Protocol file			07/05/2025	No	No
Statistical Analysis Plan			07/05/2025	No	No