

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	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/12/2024	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/05/2025	Condition category Surgery	<input type="checkbox"/> 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?

Ha Quoc Hung M.D., haquochungmd@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Hung Quoc Ha

ORCID ID

<https://orcid.org/0000-0002-4830-3954>

Contact details

215 Hong Bang, Ward 11, District 5

Ho Chi Minh

Viet Nam

700000

+84 364 216 520

hquhung.nt22@ump.edu.vn

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Efficacy

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

75 years

Sex

All

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
Ho Chi Minh
Viet Nam
700000

Sponsor information

Organisation

University Medical Center HCMC

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

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?
Basic results		07/05/2025	07/05/2025	No	No
Participant information sheet			24/12/2024	No	Yes
Protocol file			07/05/2025	No	No
Statistical Analysis Plan			07/05/2025	No	No