

Comparing pain relief methods for keyhole bowel surgery: A study on two types of nerve blocks

Submission date 18/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/11/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to compare two pain relief methods used after keyhole bowel surgery. The goal is to find the most effective way to reduce pain and minimize the need for morphine, which can have side effects. The two methods being compared are the quadratus lumborum (QL) block and the transversus abdominis plane (TAP) block.

Who can participate?

Patients who are undergoing laparoscopic (keyhole) colorectal surgery can participate in this study.

What does the study involve?

Participants will be randomly assigned to one of two groups: one group will receive the QL block, and the other will receive the TAP block. Both groups will receive general anesthesia during surgery. After the surgery, participants will receive one of the two pain relief methods. All participants will also receive standard pain relief medications, including paracetamol, nefopam, and patient-controlled analgesia (PCA).

What are the possible benefits and risks of participating?

Participants may benefit from effective pain relief from one of the two methods. Both methods have been shown to reduce pain after laparoscopic colorectal surgery. There is a very small risk of complications related to anesthesia, but these are rare and will be closely monitored by medical staff.

Where is the study run from?

Binh Dan Hospital (Viet Nam)

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 of Medicine and Pharmacy at Ho Chi Minh City Medicine and Pharmacy University (Viet Nam)

Who is the main contact?
Mr Van Phuoc Toan, dr.toanvan@gmail.com

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 quadratus lumborum block and transversus abdominal plane block in laparoscopic colorectal surgery

Study objectives

Quadratus lumborum anesthesia reduces morphine consumption 48 hours postoperatively by 50% compared with transverse abdominal plane anesthesia in laparoscopic colorectal surgery

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 22/10/2024, Ethics council in biomedical research, University of Medicine and Pharmacy (217 Hong Bang, Ward 11, District 5, Hochiminh city, 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**Health condition(s) or problem(s) studied**

Analgesic after laparoscopic colorectal surgery

Interventions

All patients recruited into the study will be randomized into 2 groups: GL group (quadra lumbar muscle block group) and TAP group (transversus abdominis plane block group) by creating a block random number table in Excel software 2016 (copyrighted by the Department of Public Health - Ho Chi Minh City University of Medicine and Pharmacy). Choosing the RAND function with the sort A->Z command will give you similar random numbers corresponds to the serial number of the patients in the research sample. Choose an odd number QL group and even numbers for TAP group.

The patient is induced, intubated and maintained according to the protocol hospital. At the end of surgery: After the last stitch of skin is sutured, the patient is fine perform QL or TAP according to initial randomization.

Both methods are performed under ultrasound guidance. The anesthetic used is ropivacaine 0.25% 20ml for each side.

Post-operative analgesia includes: patient-controlled analgesia (PCA) with morphine, paracetamol 1gr per 8h, nefopam 20mg per 8h.

Intervention Type

Procedure/Surgery

Primary outcome measure

Total dose of morphine-PCA 48 hours after surgery measured using patient records

Secondary outcome measures

Measured using patient records:

1. Total dose of morphine-PCA at postoperative time points (1 hour, 2 hours, 6 hours, 12 hours, 24 hours)
2. VAS pain scores at rest and movement at postoperative times (1 hour, 2 hours, 6 hours, 12 hours, 24 hours, 48 hours)
3. Postoperative nausea and vomiting (PONV)
4. Opioid sedation (POSS)
5. Abdominal skin sensory area after 1 hour of blockade.

Overall study start date

01/07/2024

Completion date

30/09/2025

Eligibility

Key inclusion criteria

1. The patient is indicated for elective laparoscopic colorectal surgery
2. Patients are 18 to 70 years old
3. Patients' health status is assessed according to the Society of Anesthesiology and Resuscitation United States (ASA) at level I-III

Participant type(s)

Resident

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Patients addicted to opioid drugs
2. Do not understand the instructions for using the PCA device
3. History of chronic pain, anesthetic allergy
4. Obese patients have BMI over 30 kg/m²
5. The patient converted from laparoscopic surgery to open surgery

Date of first enrolment

11/11/2024

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

Viet Nam

Study participating centre

Binh Dan Hospital, Hochiminh city

371 Dien Bien Phu - Ward 4 - District 3

Hochiminh city

Viet Nam

700000

Sponsor information

Organisation

Binh Dan Hospital

Sponsor details

371 Dien Bien Phu - Ward 4 - District 3

Ho Chi Minh

Viet Nam

700000

+84 28 3839 4747

bvbinhdan@hcm.vnn.vn

Sponsor type

Hospital/treatment centre

Website

<https://bvbinhdan.com.vn/>

Funder(s)

Funder type

University/education

Funder Name

University of Medicine and Pharmacy at Ho Chi Minh City Medicine and Pharmacy University

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

30/06/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

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dr.toanvan@gmail.com

IPD sharing plan summary

Stored in non-publicly available repository