RESEARCH INFORMATION SHEET AND CONSENT FORM FOR PARTICIPANTS

Study title: Comparison of analgesic efficacy between quadratus lumborum block and transversus abdominal plane block in laparoscopic colorectal surgery.

Sponsor: Binh Dan Hospital

Principal Investigator: Van Phuoc Toan

Contact number: 090 299 3591

Host institution: Department of Anesthesiology, Binh Dan Hospital

I. INFORMATION ABOUT THE STUDY

Dear Sir/Madam,
I would like to provide you with the following information and respectfully invite you to participate in this study.

Study purpose
The aim of this study is to compare the analgesic efficacy of two postoperative pain management techniques in laparoscopic colorectal surgery, in order to identify the more effective method, minimize adverse effects from opioid analgesics, provide greater benefits for patients, facilitate better recovery, and improve treatment quality.

Method 1: Transversus Abdominis Plane (TAP) block
- Advantages: Effective postoperative analgesia, technically easy to perform
- Disadvantages: Short duration of effect, limited efficacy for supraumbilical incisions

Method 2: Quadratus Lumborum (QL) block
- Advantages: Effective postoperative analgesia, longer duration of pain relief
- Disadvantages: Technically more challenging than TAP block

Study process
- Study period: November 2024 – June 2025
- The study requires at least 60 patients, randomized into 2 groups of 30 patients each.
- If you agree to participate, you will sign this informed consent form and be randomly assigned to either the QL block group or the TAP block group. Participation will not affect your surgical procedure.
- In the operating room, all patients will undergo general anesthesia with endotracheal intubation for laparoscopic colorectal surgery as per Binh Dan Hospital's protocol.
- At the end of surgery, the anesthesiologist will perform either a QL block or a TAP block. The choice is randomized and unknown beforehand.
- After surgery, all patients will receive the same analgesic regimen:
  + Paracetamol 1 g every 8 hours (3 times/day)

+ Nefopam 20 mg every 8 hours (3 times/day)
+ Patient-controlled analgesia (PCA)

- All drugs used in this study are approved by the U.S. FDA and the Vietnamese Drug Administration.

Benefits of participation

You will benefit from the analgesic effects of one of the two pain management techniques. Both methods have been proven effective for postoperative pain in laparoscopic colorectal surgery.

Risks of participation

- If you do not participate: You may still experience perioperative risks and complications related to surgery and anesthesia, as outlined in the consent form you signed for surgery.
- If you participate: Very rarely, complications related to local anesthetics (e.g., local anesthetic systemic toxicity) or the block technique (e.g., inadvertent puncture of blood vessels or intra-abdominal organs) may occur. Any side effects or complications will be managed according to departmental protocols, with physicians and nurses closely monitoring your condition to prevent and treat adverse events.

Costs

You will pay the same treatment costs as non-participants, including: surgical fees, pre/intra/postoperative medical care, postoperative analgesia package, use of medical equipment and supplies, medications, and IV fluids.

Compensation/treatment for study-related complications

If a complication directly related to the nerve block occurs, the investigator is responsible for your treatment. You will not bear any costs for the management of such block-related complications.

Voluntary participation

Participation in this study is entirely voluntary. No one will pressure or coerce you. You may withdraw at any time without affecting your surgical care or hospital treatment.

Confidentiality

All personal information will be coded and stored in the investigator's password-protected computer. Data will be used solely for research purposes and remain strictly confidential.

II. CONSENT TO PARTICIPATE

I have read and understood the above information. I have had the opportunity to review and ask questions regarding the study. I have spoken directly with the investigator and received satisfactory answers to all my questions. I have received a copy of this Information Sheet and hereby voluntarily consent to participate in this study.

Participant's signature:

Name _____ Signature _____

Date _____

Investigator/consent taker's signature:
I, the undersigned, confirm that the patient/volunteer who signed this consent form has read the above information sheet. The study details, risks, and benefits were thoroughly explained to the participant, who has clearly understood them.

Name _____ Signature _____
Date _____