

# Comparing pain relief methods for digestive surgery patients: intravenous lidocaine versus an abdominal block injection

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<b>Registration date</b> 07/02/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2025	<b>Condition category</b> 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

Most abdominal surgeries require various incisions, including midline cuts. Pain management should be safe, and effective, and not limit movement. Local anesthetics like intravenous lidocaine (IVL) or lateral transabdominal plane (TAP) block can reduce opioid use. This study compares the effects of IVL and lateral TAP block on NRS scores and fentanyl rescue analgesia use in digestive surgery patients with midline incisions.

### Who can participate?

Adult digestive surgery patients with midline incisions

### What does the study involve?

In this study, participants will be randomly assigned into two groups: one receiving IVL and the other receiving lateral TAP block. The level of pain will be assessed by a numeric rating scale at baseline, 6h, 12h, 18h, and 24h, as well as whether rescue analgesia is required to be administered if NRS  $\geq$  4.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Adam Malik Hospital, Pirnagdi General Hospital, Haji Hospital

### When is the study starting and how long is it expected to run for?

September 2024 to January 2025

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr. Andriamuri Primaputra Lubis, [andriamuri@usu.ac.id](mailto:andriamuri@usu.ac.id)

## Contact information

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Public, Scientific

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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 the effectiveness of intravenous lidocaine (IVL) and lateral trans abdominal plane (TAP) block on the numeric rating scale (NRS) in digestive surgery patients with midline incision

## **Study objectives**

The use of the lateral TAP Block is more effective in reducing NRS scores and the need for rescue analgesia compared to the use of IVL

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 06/09/2024, Health Research Ethics Committee of Universitas Sumatera Utara (dr. T. Mansur No. 66 Lt II RS. Prof. dr. Chairuddin P. Lubis, Kampus USU, Medan, 20155, Indonesia; +62-61-8211045; komiteetik@usu.ac.id), ref: 1122/KEPK/USU/2024

## **Study design**

Single-blind randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Digestive surgery patients with midline incisions

## **Interventions**

This study is a randomized single-blind controlled clinical trial, where the participants or research subjects are unaware of the group they belong to and the researchers are aware of this information. The study includes both a control group and an intervention group to compare the effects of Intravenous Lidocaine (IVL) and Lateral Trans Abdominal Plane (TAP) Block on the NRS (Numeric Rating Scale) scores in patients following digestive surgery with a midline incision. The research subjects were selected using a consecutive sampling technique until the required sample size was reached. Data collection was conducted from March to August 2024.

Randomization was carried out by volunteers using computer-generated randomization through the website [www.randomizer.org](http://www.randomizer.org). The participants were divided into two groups: Group A (Intravenous Lidocaine Group) and Group B (Lateral Trans Abdominal Plane (TAP) Block Group). Patients in Group A (Intravenous Lidocaine Group) are administered a lidocaine loading dose of 1 mg/kg, followed by a maintenance dose of 1.5 mg/kg/hour after induction, continuing for 1 hour postoperatively. In Group B (Lateral Trans Abdominal Plane (TAP) Block Group), 20 cc of 0.25% ropivacaine is administered after the surgery, with ultrasound guidance used to perform the block. The ultrasound probe is placed on each lateral abdominal wall at the mid-axillary line, between the lower costal margin and the iliac crest, with a total of 40 cc of 0.25% ropivacaine

being administered. The subjects were followed up at several time points (6 hours, 12 hours, 18 hours, and 24 hours post-surgery) to assess the Numeric Rating Scale (NRS) and the administration of rescue analgesics, with a total follow-up duration of 24 hours in both arms.

### **Intervention Type**

Drug

### **Pharmaceutical study type(s)**

Pharmacodynamic

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Lidocaine

### **Primary outcome measure**

Pain is measured using a Numeric Rating Scale (NRS) at baseline, 6h, 12 h, 18 h, and 24 h

### **Secondary outcome measures**

The need for rescued analgetic measured using an NRS  $\geq 4$  at 6, 12, 18, and 24 h

### **Overall study start date**

01/09/2024

### **Completion date**

10/01/2025

## **Eligibility**

### **Key inclusion criteria**

1. Willing to participate in the study
2. Patients aged 18-65 years
3. ASA I to III
4. Undergoing digestive surgery with a midline incision, with the highest incision level corresponding to dermatomes T6-T10

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

65 Years

### **Sex**

Male

**Target number of participants**

48

**Total final enrolment**

48

**Key exclusion criteria**

1. Contraindications to nerve block such as coagulation dysfunction or infection at the puncture site, history of allergy to local anesthetics
2. Cardiac arrhythmia prior to surgery
3. Chronic pain (persistent pain lasting more than 6 months)
4. Long-term use of opioid analgesics or corticosteroids
5. Pregnancy
6. History of drug abuse or mental illness, or communication disorders
7. Neurological deficits

**Date of first enrolment**

05/09/2024

**Date of final enrolment**

30/01/2025

## **Locations**

**Countries of recruitment**

Indonesia

**Study participating centre**

**Adam Malik Hospital**

Jl. Bunga Lau No.17, Kemenangan Tani, Kec. Medan Tuntungan

Medan

Indonesia

20136

**Study participating centre**

**Haji Hospital Medan**

l. Rumah Sakit H. No.47, Kenangan Baru, Kec. Percut Sei Tuan

Medan

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**Study participating centre**

**Pirngadi General Hospital**

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## Sponsor information

**Organisation**

University of North Sumatra

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**Sponsor type**

University/education

**Website**

<https://usu.ac.id>

**ROR**

<https://ror.org/01kknrc90>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/03/2025

**Individual participant data (IPD) sharing plan**

The data sets generated during and /or analysed during the current study will be published as a supplement to the results publication

**IPD sharing plan summary**

Published as a supplement to the results publication