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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
05/01/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
07/02/2025	Completed	Results
Last Edited	Condition category	Individual participant data
16/01/2025	Surgery	[X] 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 with 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

# Contact information

## Type(s)

Public, Scientific

#### Contact name

Mr Andriamuri Lubis

## Contact details

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#### Type(s)

Principal investigator

#### Contact name

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

## Study type(s)

Treatment

#### 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. 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

#### Phase

**Not Specified** 

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

Lidocaine

#### Primary outcome(s)

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

## Key secondary outcome(s))

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

# 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** 

## Healthy volunteers allowed

No

# Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

65 years

#### Sex

Male

#### 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 Indonesia 20371

# Study participating centre

# Pirngadi General Hospital

Jl. Prof. H. M. Yamin No.47, Perintis, Kec. Medan Tim., Kota Medan, Medan Indonesia 20234

# **Sponsor information**

#### Organisation

University of North Sumatra

#### **ROR**

https://ror.org/01kknrc90

# Funder(s)

#### Funder type

Other

#### Funder Name

Investigator initiated and funded

# **Results and Publications**

## 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