

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

Submission date 05/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/01/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data <input 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

Contact information

Type(s)

Public, Scientific

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Additional identifiers

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 analgetic 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

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Study participating centre

Pirngadi General Hospital

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

Medan

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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