ISRCTN18079505 https://doi.org/10.1186/ISRCTN18079505

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/02/2025	**Overall study status** Completed	
Last Edited 16/01/2025	**Condition category** Surgery	

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 ≥ 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
Tasbih Block I No 66 Lk Tanjung Sari Kecamatan Medan Selayang
Medan
Indonesia
20131
+62 08126078194
andriamuri@usu.ac.id

Type(s)
Principal investigator

Contact name
Mrs prasetyo tri nugroho

Contact details
Jl. Ampera II, Sei Sikambing C-II, Medan Helvetia, 20122
Medan
Indonesia
20122
+6282249356633
dr.prasetyotrinugroho@gmail.com

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 analgetic measured using an NRS ≥ 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