ISRCTN31659103 https://doi.org/10.1186/ISRCTN31659103

Comparison of lidocaine spray 10% vs. lidocaine gel 2% for preventing post-intubation and post-extubation complications

Submission date
04/01/2025

Recruitment status
No longer recruiting

Registration date
01/02/2025

Overall study status
Completed

Last Edited
16/01/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study focuses on airway management during anesthesia, specifically the process of intubation and extubation. These procedures are essential for keeping the airway open and ensuring proper breathing. However, they come with risks, especially during extubation, such as coughing, airway blockage, and increased heart rate. The study aims to compare the effectiveness of lidocaine spray and gel in reducing these complications, particularly postoperative sore throat (POST) and other issues after surgery.

Who can participate?
Adults aged 18 to 64 years who are undergoing surgery with general anesthesia and endotracheal intubation (GA-ETT), classified as ASA I and II, and whose surgery lasts less than 2 hours can participate.

What does the study involve?
Participants will be divided into three groups:
Group A will receive 10% lidocaine spray at a dose of 1.5 mg/kg body weight.
Group B will receive 2% lidocaine gel at a dose of 1.5 mg/kg body weight.
Group C will receive a saline solution (0.9% NaCl).
All groups will undergo hemodynamic assessments, reflex evaluations, and checks for airway trauma at 2 hours and 24 hours after surgery.

What are the possible benefits and risks of participating?
Possible benefits:
Reduced complications like sore throat, coughing, and airway irritation after intubation and extubation.
Alleviation of discomfort such as sore throat and difficulty swallowing.
More frequent monitoring of vital signs and airway condition, leading to early detection and management of complications.
Contribution to research that could improve anesthesia practices and benefit future patients.
Possible risks:

Local irritation or allergic reactions to lidocaine, such as redness or swelling.
Risk of airway issues like obstruction or laryngospasm if lidocaine is not effective.
Potential systemic side effects from high doses of lidocaine, including dizziness or more severe effects like seizures.
The possibility that lidocaine may not prevent complications for all participants.
Where is the study run from?
The study is being conducted at several hospitals in Medan, Indonesia: Adam Malik Hospital, Putri Hijau Level II Military Hospital, North Sumatra University Hospital, and Dr. Pirngadi General Hospital.

When is the study starting and how long is it expected to run for?
September 2024 to February 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
The main contact for the study is Andriamuri Primaputra Lubis, who can be reached at andriamuri@usu.ac.id.

Contact information

Type(s)
Public, Scientific, Principal investigator

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

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison of the use of lidocaine spray vs lidocaine gel for post-intubation and post-extubation complications

Acronym
CULSLGFPIPEC

Study objectives
2% lidocaine gel is more effective to lower pain assessment 2 hours post-extubation compared to the treatment group using 10% lidocaine spray.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/09/2024, Health Research Ethics Committee of Universitas Sumatera Utara (T. Mansur Street, No. 66, Medan, North Sumatera, Medan, 20155, Indonesia; +62 61 8211045; komiteetik@usu.ac.id), ref: 1108/ KEPK/USU/2024

Study design
Experimental analytical study with a non-randomized design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Elective surgery patients

Interventions
This study is an experimental analytical research with a randomized controlled trial (RCT) design aimed at comparing the effectiveness of 10% Lidocaine Spray and 2% Lidocaine Gel in managing post-intubation and post-extubation complications in patients undergoing elective surgical procedures. The subjects will be randomized using computer-generated randomization through the website randomizer.org. Participants will be divided into three groups: Group A (10% Lidocaine Spray), Group B (2% Lidocaine Gel), and Group C (control group). Group A will receive 10% Lidocaine Spray at a dose of 1.5 mg/kg body weight, Group B will receive 2% Lidocaine Gel at a dose of 1.5 mg/kg body weight, and Group C will receive 0.9% NaCl (saline solution).

The subjects will be followed up at several time points (2 hours and 24 hours post-surgery) to assess post-extubation complications and the need for rescue analgesics, with a total follow-up duration of 24 hours. In the case of post-extubation complications, patients will receive rescue medication in the form of dexamethasone 0.2 mg/kg, after obtaining approval from the attending physician

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
2% lidocaine gel and 10% lidocaine

Primary outcome(s)
1. Diastolic Blood Pressure is measured using Non-invasive Blood Pressure at baseline, 2 hours, and 24 hours post-surgery
2. Systolic Blood Pressure is measured using Non-invasive Blood Pressure at baseline, 2 hours, and 24 hours post-surgery
3. Heart rate (Pulse) is measured using monitor at baseline, 2 hours, and 24 hours post-surgery
4. Postoperative Sore Throat (POST) is measured using Post Scoring at baseline, 2 hours, and 24 hours post-surgery
5. Post-extubation complication are assessed using vital signs assessment by monitor (Systolic and diastolic blood pressure, patient's heart rate) at baseline, 2 hours, and 24 hours post-surgery

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
02/02/2025

Eligibility

Key inclusion criteria
1. Patients undergoing surgery
2. General Anesthesia and Endotracheal Tube (GA-ETT)
3. Aged between 18 and 64 years
4. Classified as ASA (American Society of Anesthesiologists) I or II
5. Surgeries lasting less than 2 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
All

Total final enrolment
95

Key exclusion criteria
Patients predicted to encounter intubation difficulties

Date of first enrolment
15/12/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Indonesia

Study participating centre
Haji Adam Malik General Hospital Medan
Jl. Bunga Lau No.17, Kemenangan Tani, Kec. Medan Tuntungan, Kota Medan, Sumatera Utara
Medan
Indonesia
20136

Study participating centre
Putri Hijau Hospital Medan
Putri Hijau No.17, Kesawan, Kec. Medan Bar., Kota Medan
Medan
Indonesia
20111

Study participating centre
Universitas Sumatra Utara Hospital Medan
Dr. Mansyur No.66, Merdeka, Kec. Medan Baru, Kota Medan
Medan
Indonesia
20154

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 datasets generated during and/or analysed during the current study will be available upon request from Andriamuri P Lubis (andriamuri@usu.ac.id)

IPD sharing plan summary
Available on request