Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparison of the side effects of extubation during the use of intravenous lidocaine in higher and lower 50 years old people who candidate of internal laparoscopic cholecystectomy surgery.

Protocol summary

Study aim

Determining the effect of age on the side effects of octobasone when using intravenous lidocaine in people undergoing internal laparoscopic cholecystectomy surgery.

Design

The number of 122 patients with the mentioned entry criteria in two age groups under 50 years and over 50 years will be divided into two age groups of 61 people.

Settings and conduct

In the mentioned procedures, after the end of the surgical procedure and the need for extubation, 90 seconds before extubation, intravenous lidocaine with a dose of 1 mg/kg is injected to the patient, and then the criteria for laryngospasm and bronchospasm in the interval: immediately after extubation Until the time of exit from the recovery, also three parameters of sore throat, cough and aspiration will be evaluated and charted from the beginning of extubation until the time of exit from the recovery.

Participants/Inclusion and exclusion criteria

The criteria for entering this study is to be at least 18 years old and not pregnant, not having any conditions such as: heart disease, kidney and liver failure, history of cardiopulmonary resuscitation, history of respiratory disease, high blood pressure, mental retardation or psychological disease, and sensitivity to lidocaine.

Intervention groups

In this study, the intervention group includes people over 50 years old who will receive lidocaine. The control group is people who have received lidocaine but are under 50 years old.

Main outcome variables

Incidence of extubation complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230227057548N1**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Mohammad Mohammadifard

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 84 3337 5525

Email address

mmohammadifard2001@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-16, 1401/12/25

Expected recruitment end date

2024-03-15, 1402/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
comparison of the side effects of extubation during the use of intravenous lidocaine in higher and lower 50 years old people who candidate of internal laparoscopic cholecystectomy surgery.

Public title
comparison of the age effect on the side effects of extubation during the use of lidocaine
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being at least 18 years old candidate of internal laparoscopic cholecystectomy surgery consent to participate in the study
Exclusion criteria:
pregnancy heart disease liver failure history of cardiopulmonary resuscitation history of respiratory disease high blood pressure mental retardation sensitivity to lidocaine psychological illness Kidney failure
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **122**
More than 1 sample in each individual
Number of samples in each individual: **1**
In each group, intravenous lidocaine was given 90 seconds before extubation, and then the positive effects of lidocaine in improving the complications of extubation were measured.
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, consent is obtained from the participants, but no explanation is given regarding the age range that is the subject of the study, and also the information that reaches the data analyst is coded and blinded. Each of them does not know the information about which age range they are.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Ilam University of Medical Sciences
Street address
saleek street
City
ilam
Province
Ilam
Postal code
6931473414
Approval date
2023-02-28, 1401/12/09
Ethics committee reference number
IR.MEDILAM.REC.1401.268

Health conditions studied

1

Description of health condition studied
In people undergoing internal laparoscopic cholecystectomy surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
In this study, the primary outcome is the incidence of laryngospasm, which is determined and charted by the capnograph tool.
Timepoint
Immediately after extubation until exit from recovery for each patient in the study
Method of measurement
Side stream capnograph is used to measure laryngospasm.

2

Description
The incidence of bronchospasm is determined and charted by the capnograph tool.
Timepoint
Immediately after extubation until exit from recovery for each patient in the study
Method of measurement
side stream capnograph is used to measure bronchospasm.

3

Description
The amount of sore throat that will be used through the

Visual Analogue Scale.

Timepoint

Immediately after extubation until exit from recovery for each patient in the study

Method of measurement

The Visual Analogue Scale for measuring pain represents a 10 cm line printed on a piece of paper with markers at each end indicating "no pain" at one end and "worst pain" at the other end or It is "indescribable pain".

4

Description

The number of coughs counted and charted by the researcher.

Timepoint

Immediately after extubation until exit from recovery for each patient in the study

Method of measurement

The number of coughs is counted by the researcher and recorded and charted in three ranges: low, medium, and high.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: people undergoing internal laparoscopic cholecystectomy surgery, in this study, after obtaining informed consent from the patient's companion and after the completion of the surgery and the need for extubation 90 seconds before extubation, intravenous lidocaine at a dose of 1 mg/kg was injected into the patient. And after that, the parameters of laryngospasm and bronchospasm in the period after extubation until the time of leaving recovery, as well as the two criteria of sore throat and cough, from after extubation to the time of leaving recovery, will be evaluated and charted. In this study, 2% lidocaine ampoule of Caspian Tamim pharmaceutical company will be used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ilam

Full name of responsible person

mohammad mohammadifard

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

mohammad mohammadifard

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
For each patient, information such as age, gender, underlying disease, treatment services, and the patient's clinical condition are recorded before surgery, and after that, laryngospasm, bronchospasm, sore throat, cough are recorded and shared.
When the data will become available and for how long
The start of the access period is 5 months after the results are published.
To whom data/document is available
People working in medical universities of the country
Under which criteria data/document could be used
In case of research on the vital condition of patients, including heart rate, breathing rate, blood pressure before and after surgery, access will be allowed.
From where data/document is obtainable
Those who want access can send a letter to my e-mail at mmohammadifard2001@gmail.com.
What processes are involved for a request to access data/document
It is required to be a member of the University of Medical Sciences with a valid certificate and also a certificate proving the completion of a research project related to the subject, as well as the amount of information required and the reason for using this information.
Comments