Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Comparison of the convenience of tracheal extubation between two methods of filling the endotracheal cuff with lidocaine 2% and air in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim

The aim of this study is to compare the convenience of tracheal extubation between two methods of filling the Endotracheal Tube cuff with Lidocaine 2% and air in patients undergoing laparoscopic cholecystectomy.

Design

In this single-blind, two-arm, parallel-group controlled trial, 70 patients undergoing elective laparoscopic cholecystectomy will be randomly divided into two groups of filling the endotracheal tube cuff with lidocaine and air, given their documents number .

Settings and conduct

The study will be conducted in the operation room of Qazvin Velayat hospital. 0.02 mg/kg of midazolam and 2µg/kg of fentanyl will be used for premedication, 2mg/kg of propofol 1% will be used for induction of anesthesia and 0.5 mg/kg of atracurium will be used as muscle relaxant. In the Lidocaine group, the endotracheal tube cuff will be filled with lidocaine 2% and in the Air group, the cuff will be filled with air until the pressure reaches between 20 and 25 cm H2O. None of the patients were aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria will be female gender; age between 20 and 60; and class 1&2 of the American Society of Anesthesiologists (ASA) Classification. Exclusion criteria will be heart block or heart failure; unstable hemodynamics; depression; kidney or liver failure; lidocaine sensitivity; tracheal deformity; and lack of consent to partipate in study.

Intervention groups

Intervention and control groups includes patients under general anesthesia receiving intervention of filling the endotracheal tube cuff with lidocaine and air respectively.

Main outcome variables

Study outcomes will be patient's blood pressure and heart rate before induction of anesthesia, 30 and 60 minutes after induction, and before and after extubation; complications of intubation, including bucking, coughing and sore throat during recovery, 6 and 12 hours later.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150803023473N5**
Registration date: **2020-01-06, 1398/10/16**
Registration timing: **retrospective**

Last update: **2020-01-06, 1398/10/16**
Update count: **0**

Registration date

2020-01-06, 1398/10/16

Registrant information

Name

Siamak Yaghuobi

Name of organization / entity

Qazvin University of Medical Sciences & Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-03-20, 1397/12/29

Scientific title

Comparison of the convenience of tracheal extubation between two methods of filling the endotracheal cuff with lidocaine 2% and air in patients undergoing laparoscopic cholecystectomy

Public title

Effect of filling of endotracheal tube cuff with Lidocaine on complications of postoperative extubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female Gender Age between 20 to 60 Class 1 & 2 of the American Society of Anesthesiologists (ASA) Classification

Exclusion criteria:

Heart block Heart Failure Unstable hemodynamics Depression Kidney or liver failure Sensitivity to Lidocaine Tracheal deformity Lack of consent to participate in the study

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will not be aware of the way of endotracheal tube filling during anesthesia, so this study is considered a single-blind study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.QUMS.REC.1397.274

Health conditions studied

1

Description of health condition studied

Sore throat after endotracheal intubation

ICD-10 code

Y70

ICD-10 code description

Anaesthesiology devices associated with adverse incidents

Primary outcomes

1

Description

Blood pressure

Timepoint

Before induction of anesthesia, 30 and 60 minutes after induction, and before and after extubation.

Method of measurement

Blood Pressure Cuff (Sphygmomanometer)

2

Description

Heart rate

Timepoint

Before induction of anesthesia, 30 and 60 minutes after induction, and before and after extubation.

Method of measurement

Cardiac monitoring device

Secondary outcomes

1

Description

Coughing

Timepoint
During recovery, 6 hours and 12 hours after recovery
Method of measurement
Patient self-reporting

2

Description
Bucking
Timepoint
During recovery, 6 hours and 12 hours after recovery
Method of measurement
Patient self-reporting

3

Description
Sore throat
Timepoint
During recovery, 6 hours and 12 hours after recovery
Method of measurement
Patient self-reporting

Intervention groups

1

Description
Intervention group: In the Lidocaine group, the endotracheal tube cuff will be filled with lidocaine 2% until the pressure reaches between 20 and 25 cm H2O.
Category
Prevention

2

Description
Control group: In the Air group, the cuff will be filled with air until the pressure reaches between 20 and 25 cm H2O.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin Velayat hospital
Full name of responsible person
Siamak Yaghoubi
Street address
Taavon Square, 22 Bahman Blvd., Minoodar Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Karan Samimi
Position
Resident of anesthesiology
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after participants are unidentified.
When the data will become available and for how long
Start of access period from 1398
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
In order to further study on the available data
From where data/document is obtainable
Dr. Karan Samimi karansamimi@yahoo.com
What processes are involved for a request to access data/document
Obtaining permission from Research Deputy of Qazvin University of Medical Sciences
Comments