

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 participate 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)

Phone

+98 28 3376 0620

Email address

syaghoubi@qums.ac.ir

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

City

Qazvin

Province

Qazvin

Postal code

3419915315

Phone

+98 28 3379 0620

Fax

+98 28 3379 0611

Email

syaghoubi@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

Street address

Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

3419915315

Phone

+98 28 3333 6001

Email

syaghoubi@qums.ac.ir

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

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Bahonar Blvd.,

City

Qazvin

Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Fax
Email
karansamimi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Siamak Yaghoubi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Bahonar Blvd.,
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Email
syaghoubi@qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Karan Samimi
Position
Resident of anesthesiology
Latest degree

Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Bahonar Blvd.,
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Email
karansamimi@yahoo.com

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