

# 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 H<sub>2</sub>O. 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

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#### Province

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#### Postal code

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#### Phone

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## 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.

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#### Province

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#### Phone

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#### 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.,

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Siamak Yaghoubi  
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Assistant Professor  
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Specialist  
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## Person responsible for updating data

### Contact

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Qazvin University of Medical Sciences  
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Karan Samimi  
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**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