

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison the effect of the I-gel with the cuffed tracheal tube in Patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim

The purpose of this study is evaluation the effect comparison the effect of the I-gel with the cuffed tracheal tube in Patients undergoing laparoscopic cholecystectomy

Design

Patients will be divided into two groups by random number table. It does not apply. Study will be performed on 60 Patients.

Settings and conduct

In Urmia Imam Khomeini hospital operating room after induction of general anesthesia in operating room , either an I-gel or endotracheal tube will insert by the experienced anesthesiologists. After successful insertion, the difference between the inspired and expired tidal volumes is used to calculate the leak volume, mean airway pressure by ventilator manometer and incidence of sore throat in recovery will measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: American Society of Anesthesiologists physical status I or II, Aged 18-60 years, Elective laparoscopic cholecystectomy, general anesthesia
Exclusion criteria: Chronic obstructive pulmonary disease, Body mass index $\geq 35\text{kg/m}^2$, Potential difficult intubation, increased risk of pulmonary aspiration, Pregnancy

Intervention groups

After induction of anesthesia, in study group an I-gel and in control group ETT will be inserted by the experienced anesthesiologists

Main outcome variables

Postoperative sore throat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N10**

Registration date: **2019-01-21, 1397/11/01**

Registration timing: **retrospective**

Last update: **2019-01-21, 1397/11/01**

Update count: **0**

Registration date

2019-01-21, 1397/11/01

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-11-21, 1394/08/30

Expected recruitment end date

2016-05-20, 1395/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of the I-gel with the cuffed tracheal tube in Patients undergoing laparoscopic cholecystectomy

Public title

Clinical trial the effect of the I-gel with the cuffed tracheal tube in Patients undergoing laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

American Society of Anesthesiologists physical status I or II Aged 18–60 years Elective laparoscopic cholecystectomy general anesthesia

Exclusion criteria:

Chronic obstructive pulmonary disease Body mass index $\geq 35 \text{ kg/m}^2$ Potential difficult intubation increased risk of pulmonary aspiration Pregnancy Ischemic heart disease

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the random numbers table. In this way, the researcher gives each individual a code or a special number. Then it uses numbered numerals, and if not, list each of them on paper or small paperboard. Therefore, the number of people in the community will have a number of nuts or plaque. Then they will pour them inside a bag or container. Then remove the beads one by one, and Notices the number of them. It will continue to do so up to the number of sample numbers to choose. When the number of sample people was completed and drawings is completed, according to the list, identifies its sample people.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is one-way blind. In this study, only the patient will be unaware of which group to be assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2015-10-28, 1394/08/06

Ethics committee reference number

IR.UMSU.REC.1394.232

Health conditions studied

1

Description of health condition studied

Sore throat

ICD-10 code

J06.0

ICD-10 code description

Acute laryngopharyngitis

Primary outcomes

1

Description

sore throat

Timepoint

in recovery

Method of measurement

visual analog scale

Secondary outcomes

1

Description

end tidal CO_2

Timepoint

Before and after blowing gas

Method of measurement

capnography, mmHg

2

Description

Mean airway pressure

Timepoint

Before and after blowing gas

Method of measurement

Manometer Ventilator, Centimeter H₂O

3

Description

Leak Volume

Timepoint

during surgery

Method of measurement

Difference Between Ventilation Volume At Inspiration Time And Expiration Time.This volume will be measured by a ventilator manometer.

Intervention groups

1

Description

Intervention group: insertion of i-Gel

Category

Treatment - Devices

2

Description

Control group: insertion of tracheal tube

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital, A operating room

Full name of responsible person

Shahryar Sane ,Associate Professor, Anesthesiologist

Street address

Modarres Avenue, Ershad Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

دانشیار

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available