

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

A comparative study between endotracheal tube and I-GEL in gynecological laparoscopic surgeries under general anesthesia; A double blind clinical trial study

Protocol summary

Study aim

A comparative study between the endotracheal tube and I-GEL in gynecological laparoscopic surgeries under general anesthesia

Design

A double-blinded and randomized clinical trial with parallel groups design of 92 patients.

Settings and conduct

This study is conducted as a clinical trial in Alzahra Hospital in Rasht. After explaining the purpose and method of the research, informed consent will be obtained. The patient will be in the supine position and standard monitoring will be established. After pre-oxygenation with 100% oxygen, induction of anesthesia will be done. Then mechanical ventilation will be established in two groups. All patients will be operated by one anesthesiologist, one anesthetic method, one surgeon, and one laparoscopy instrument. This study will be double-blinded and patients, the evaluator and the surgeon will be unaware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective laparoscopic surgeries, full fasting time of 8 hours, no history of reflux, age range between 18-55 years, duration of the operation less than two hours. Exclusion criteria: Having any pathological problems in the neck and upper airway, high risk for aspiration, failure to open the mouth more than 2.5 centimeters, emergency surgery

Intervention groups

Intervention group A: In the endotracheal tube group, after the laryngoscopy of the patient by the anesthesiologist, the patient will be intubated with an appropriate size endotracheal tube according to the patient's condition. Intervention group B: In the I-gel group, first, the appropriate size of I-gel will be selected for the patient based on the patient's weight. The I-gel will then be moistened with crystalloid and inserted by

the anesthesiologist.

Main outcome variables

Difficulty of establishing the airway, Surgeon's satisfaction with the operation field in terms of gastric dilatation, Airway pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170314033069N6**

Registration date: **2023-08-07, 1402/05/16**

Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**

Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Gelare Biazar Biazar

Name of organization / entity

Guilan University of Medical Sciences, Alzahra Hospital

Country

Iran (Islamic Republic of)

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+98 13 3336 9024

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biazar@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study between endotracheal tube and I-GEL in gynecological laparoscopic surgeries under general anesthesia; A double blind clinical trial study

Public title
Comparison of tracheal intubation and I-GEL in gynecology laparoscopic surgery under general anesthesia

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Elective laparoscopic surgeries Full fasting time of 8 hours No history of reflux American Society of Anesthesiologists (ASA) I,II Age range between 18-55 years The duration of the operation is less than two hours Body mass index (BMI) range between 25-35 kg.m2
Exclusion criteria:
Having any pathological problems in the neck and upper airway Patients at high risk for aspiration (Hiatus hernia , gastroesophageal reflux) Failure to open the mouth more than 2.5 centimeter Emergency surgery Patients with non-observance of standard times for liquids and solids (2 hours before the operation of clear liquids, 6-7 hours of solid foods)

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to two groups A, intubation with tracheal tube and B: I-gel by a random sequence created in blocks of four by WinPepi software, which was created by a statistical consultant and will be performed by a technician who is not aware of the goals of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be double-blinded. Before entering the surgeon to the operating room, induction of anesthesia and establishment of the airway will be done by the anesthesiologist, and anesthesia curtains will be placed.

Then, during the procedure, a trained medical student will collect information. In this way, the patient, the evaluator (medical student), and the surgeon who reports satisfaction are unaware of the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
City
Rasht
Province
Guilan
Postal code
4144654839
Approval date
2023-07-26, 1402/05/04
Ethics committee reference number
IR.GUMS.REC.1402.243

Health conditions studied
1
Description of health condition studied
Comparison of two methods of tracheal intubation and I-GEL in gynecology laparoscopic surgery under general anesthesia
ICD-10 code
Y70.1
ICD-10 code description
Therapeutic (nonsurgical) and rehabilitative anesthesiology devices associated with adverse incidents

Primary outcomes
1
Description
Difficulty of establishing the airway
Timepoint
3 minutes after induction of anesthesia
Method of measurement
Number of attempts to establish the airway

2

Description

Surgeon's satisfaction with the operation field in terms of gastric dilatation

Timepoint

After surgery

Method of measurement

Scoring from 0 (an empty stomach) to 10 (a fully distended stomach)

3

Description

Postoperative complications

Timepoint

After surgery

Method of measurement

Observation

4

Description

Airway pressure

Timepoint

After establishing the airway

Method of measurement

Ventilator

Secondary outcomes

1

Description

Hemodynamic changes

Timepoint

Five stations (before pneumoperitoneum, 15 minutes after pneumoperitoneum, 30 minutes after pneumoperitoneum, immediately after gas release and 15 minutes after gas release)

Method of measurement

Monitoring

Intervention groups

1

Description

Intervention group 1: In the endotracheal tube group, after the laryngoscopy of the patient by the anesthesiologist, the patient will be intubated with an appropriate size 7 or 7.5 tracheal tube depending on the patient's condition. If it was not possible to pass the tracheal tube through the vocal cords for the first time, laryngoscopy will be performed again. If the patient cannot be intubated (in two attempts), he will be excluded from the study.

Category

Treatment - Devices

2

Description

Intervention group 2: In the I-gel group, first the right size of I-gel will be selected for the patient. The size of the I-gel is determined based on the patient's weight. Accordingly, for patients weighing 30-50 kilograms Number 3, for 50-90 kilograms Number 4, and for those above 90 kilograms Number 5 will be suitable. After choosing the right size for the patient, the I-gel will be moistened with crystalloid and then the placement of the I-gel will be done by the anesthesiologist. If adequate ventilation is not established after two attempts, the procedure will be considered a failure and the patient will be excluded from the study.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr Gelareh Biazar

Street address

Alzahra Hospital, Shahid Siadati Avenue, Namjoo Street, Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

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

Rasht 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

Anesthesiology Research Center, Alzahra Hospital,
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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dr Gelareh Biazar

Position

associate professor, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Mohadese Ahmadi

Position

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Master

Other areas of specialty/work

Research Expert

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr Gelareh Biazar

Position

associate professor, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Not decided yet

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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