Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 13 3336 9024

Email address

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
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3332 9524
Email
alzahra@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Naghipoor
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
City
Rasht
Province
Guilan
Postal code
6694941446
Phone
+98 13 3333 5821
Email
naghi@gums.ac.ir
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

Person responsible for general 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
Anesthesiology Research Center, Alzahra Hospital, Namjoo Street, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3332 9524
Fax
+98 13 3336 9024
Email
gelarehbiazar1386@gmail.com
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
Anesthesiology Research Center, Alzahra Hospital, Namjoo Street, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3332 9524
Fax
+98 13 3336 9024
Email
gelarehbiazar1386@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohadese Ahmadi
Position
Research Expert/(MSc) English
Latest degree
Master
Other areas of specialty/work
Research Expert
Street address
Anestesiology Reseaech Center, Alzahra Hospital, Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3336 9328
Email
p.ahmadi2311@gmail.com
Web page 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