Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

comparing the use of tracheal tube size 7.5 and 6.5 in men and 7 and 6 in women during laparoscopic surgery in terms of reducing the incidence of sore throat and hoarseness after intubation

Protocol summary

Study aim
Determining the amount of sore throat and voice harshness after surgery following the use of tracheal tube size 6.5 instead of 7.5 in men and size 6 instead of 7 in women during laparoscopic surgery.

Design
In this study, all patients with a fixed drug regimen including propofol, atracurium, sufentanil and midazolam are under anesthesia, and propofol, remifentanil and atracurium are also used during anesthesia.The settings of the anesthesia machine are also done by the anesthesiologist based on the patient's weight and ETCO2 during anesthesia. Laryngoscopy procedure with Mackintosh blade is performed by a trained anesthesiology resident with at least two years of experience or an anesthesiologist, and the Cormack-Lehan grade is recorded by them. In this study, patients are randomly assigned to the intervention and control groups based on the last digit of the case number, whether it is an even number or an individual.

Settings and conduct
Hospitals of Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria
Patients aged 18 to 60 who are candidates for laparoscopic surgery with a BMI below 35 referring to Qaim (AH) and Imam Reza (AS) hospitals, who are in the clinical status of ASA I and II.

Intervention groups
For male patients, tracheal tube number 7.5 will be placed in the control group and tracheal tube number 6.5 in the test group. Tracheal tube number 7.0 will be placed in female patients of the control group and tracheal tube number 6.0 in female patients of the test group.

Main outcome variables
Assessment of postoperative sore throat and voice severity (according to the patient's statement)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230825059253N1**
Registration date: **2024-02-03, 1402/11/14**
Registration timing: **retrospective**

Last update: **2024-02-03, 1402/11/14**
Update count: **0**

Registration date
2024-02-03, 1402/11/14

Registrant information

Name
Pooria Namaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 2776

Email address
namaeip4001@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

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
comparing the use of tracheal tube size 7.5 and 6.5 in men and 7 and 6 in women during laparoscopic surgery in terms of reducing the incidence of sore throat and hoarseness after intubation

Public title
The effect of reducing the size of the intubation tube on the amount of sore throat after surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18-60 years old candidates for laparoscopic surgery BMI below 35 ASA I or II clinical status.

Exclusion criteria:
history of allergies and respiratory diseases history of respiratory infection during the last month History of cold or respiratory infection in the last month History of esophageal reflux Patients who fall into four Cormak-Lehane classifications during laryngoscopy Any disturbance in hemodynamics or oxygen delivery to the patient during anesthesia Need more than two laryngoscopy directions for intubation Even in patients with a BMI below 35, if re-intubation is needed due to the need to replace the tracheal tube due to overinflation Patients whose surgery lasts more than 3 hours

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

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is done based on the last digit of the file number, and in patients with an even file number, a larger tube size is used, and in patients with an odd file number, a smaller tube size is used.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, only the study participants are unaware of the size of the tube used, and due to the fact that the variable is the size of the tube, there is no possibility of blinding the clinical caregiver.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Educational, Research and Treatment Center of Imam Reza Hospital - Mashhad University of Medical Sci

Street address
No. 20, Shahid Kaveh St., Malek Shaara St., Anuri St., 2 Anuri St

City
mashhsd

Province
Razavi Khorasan

Postal code
9177795915

Approval date
2023-07-24, 1402/05/02

Ethics committee reference number
IR.MUMS.IRH.REC.1402.112

Health conditions studied

1

Description of health condition studied
Sore throat after surgery

ICD-10 code
J04.0

ICD-10 code description
Acute laryngitis

Primary outcomes

1

Description
Evaluation of postoperative sore throat and voice severity (according to the patient's statement)

Timepoint
at 1, 6, and 24 hours after surgery

Method of measurement
based on VAS criteria

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group consists of men who meet the conditions for entering the study, for whom we place an endotracheal tube number 6.5, which are compared with the control group of men who are placed with an endotracheal tube number 7.5.

Category
Treatment - Devices

2

Description
Intervention group: The second intervention group includes women who meet the conditions for entering the study, for whom we place an endotracheal tube number 6, which are compared with the control group of women who are placed with an endotracheal tube number 7.

Category
Treatment - Devices

3

Description
Control group: The first control group of men with conditions for entering the study, for whom we place an endotracheal tube No. 7.5, which are compared to the first intervention group for which we place an endotracheal tube No. 6.5.

Category
Treatment - Devices

4

Description
Control group: The second control group of women with conditions to enter the study, for whom we place an endotracheal tube number 7, which are compared to the second intervention group for which we place an endotracheal tube number 6.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospitals of Mashhad University of Medical Sciences

Full name of responsible person
Pooria Namaei

Street address
Shahid Kaveh Blvd. - Malek Shaara St. - Anuri St. - Anuri 2 - No. 20

City
mashhad

Province
Razavi Khorasan

Postal code
9177795915

Phone
+98 51 3840 2776

Email
namaeip4001@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research assistant of Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
University of Medical Sciences, 3rd floor, University Research and Technology Vice-Chancellor, University of Medical Sciences, University of Medical Sciences, University of Medical Sciences, University Street, University Street, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177795915

Phone
+98 51 3841 1838

Email
TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Pooria Namaei

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Kaveh Blvd., Anuri St., Anuri 2, No. 20

City
Mashhad

Province
Razavi Khorasan

Postal code
9177795915

Phone
+98 51 3840 2776

Email
namaeip@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoume Tabari
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913131
Phone
+98 51 3843 3999
Email
tabarim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ali Moradi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Tissue Engineering
Street address
Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913131
Phone
+98 51 3843 3999
Email
moradia@mums.ac.ir

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 will be published in the form of a research plan after deidentifying the individuals, which includes all the variables and outcomes of the study.
When the data will become available and for how long
After collecting the data and analyzing the statistics, which is about the year 1403, it will be published in the form of a research project.
To whom data/document is available
The data is accessible to all people, including researchers, institutions, universities, and industrial companies
Under which criteria data/document could be used
The information and results of the study and data are accessible to other researchers on the condition of mentioning the source of the information and data
From where data/document is obtainable
In order to receive the data, one should be in contact with the direct manager of the project, Mr. Dr. Pouria Namei, with the email address namaeip4001@mums.ac.ir, and if there are necessary conditions, the information will be provided to the people.
What processes are involved for a request to access data/document
If there is a request, an official letter of request and conditions should be sent to the email address namaeip4001@mums.ac.ir. If the necessary conditions are met, correspondence will be done with the person or institution within a week through this email to send the data.
Comments