

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, remifentanyl 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

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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 Cormack-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

mashhds

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

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Shahid Kaveh Blvd. - Malek Shaara St. - Anuri St. -
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research assistant of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

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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

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Person responsible for updating data

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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