Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of warm endotracheal tube insertion on post operation sore throat and hoarseness

Protocol summary

Summary

In this double-blind clinical trial, 124 patients aged 19 to 63 years under general anesthesia are randomly divided into intervention and control groups in case of hoarseness, no history of laryngeal surgery, and no abnormal position during operation. Patients will be excluded from the study in case of sore throat, straining, coughing during extubation and hard intubation. The intervention group will be intubated with softened endotracheal tube warmed up in 45 degrees centigrade normal saline for 5 minutes and the control group is intubated with not warmed up endotracheal tube. After anesthesia, intubation will be performed with the Supa-Tehran PVC endotracheal tube (No. 7-8 for men and 6.5-7.5 for women). Anesthesia continues with propofol, fentanyl and atracurium. The mechanical ventilation will begin with the initial tv of 10 mL/kg and the respiratory rate of 10/minute and will be adjusted with normocapnia. The effect of relaxant drugs will be reversed with Neostigmine and Atropine. When the spontaneous breathing is appropriate and the patient is able to perform oral instructions, endotracheal extubation is done immediately after suction. An airway will be inserted before the endotracheal extubation. All patients will be screened for sore throat and hoarseness severity after recovery, 2, 12 and 24 hours after surgery by an informed nurse. The severity of sore throat and hoarseness is graded and information is recorded and will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708294365N22**
Registration date: **2017-10-21, 1396/07/29**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-10-21, 1396/07/29

Registrant information

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Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Mazandaran University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of warm endotracheal tube insertion on post operation sore throat and hoarseness

Public title

Effect of warm endotracheal tube insertion on post operation sore throat and hoarseness

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Not having sore throat and clear hoarseness; no history of previous surgery of the larynx; absence of abnormal position during surgery. Exclusion criteria: Toughness; Coughing during extubation; Hard intubation (more than 2 times laryngoscopy); Nasogastric tube fixation; N2O

Age

From **19 years** old to **63 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem square, Sari

City

Sari

Postal code

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.96.3011

Health conditions studied

1

Description of health condition studied

Sore throat

ICD-10 code

J02

ICD-10 code description

Acute pharyngitis

2

Description of health condition studied

Hoarseness

ICD-10 code

R49.0

ICD-10 code description

Dysphonia

Primary outcomes

1

Description

Sore throat

Timepoint

immediately, 2 hrs, 12 hrs and 24 hrs after operation

Method of measurement

Scale of sore throat (0 without sore throat, 1 low, 2 medium, 3 severe)

2

Description

Hoarseness

Timepoint

immediately, 2 hrs, 12 hrs and 24 hrs after operation

Method of measurement

Scale of hoarseness (0 without sore throat, 1 low, 2 medium, 3 severe)

Secondary outcomes

empty

Intervention groups

1

Description

Intubation will be performed with the Supa-Tehran PVC endotracheal tube (No. 7-8 for men and 6.5-7.5 for women). The control group is intubated with not warmed up endotracheal tube

Category

Placebo

2

Description

Intubation will be performed with the Supa-Tehran PVC endotracheal tube (No. 7-8 for men and 6.5-7.5 for women). The intervention group will be intubated with softened endotracheal tube warmed up in 45 degrees centigrade normal saline for 5 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Sari
Full name of responsible person
Afshin Gholipour Baradari, MD
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research and Technology of Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeidi, MD
Street address
Moallem Square, Sari
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research and Technology of Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty