

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

###### Name

Afshin Gholipour Baradari

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3326 1245

###### Email address

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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**

Sahar Besharatdeh

**Position**

Anesthesiology resident

**Other areas of specialty/work**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

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Afshin Gholipour Baradari

**Position**

Anesthesiologist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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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*