

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of heating the tip of the endotracheal tube with warm normal saline before intubation in decreasing the prevalence of hoarseness and sore throat after removal of the tube

Protocol summary

Study aim

The effect of heating the tip of the endotracheal tube with warm normal saline before intubation in decreasing the prevalence of hoarseness and sore throat after removal of the tube

Design

A parallel, double-blind clinical trial with parallel groups, randomized by www.randomizer.at website, performed on 58 patients in the two equal groups.

Settings and conduct

This study will be done at Hazrat-e-Rasoul hospital. In the control group (n=29) the normal endotracheal tube will not be heated and in the intervention group (n=29) the endotracheal tube will be heated with normal saline 40 ° C. Eligible patients were randomly divided into two groups of heated endotracheal tube with normal saline 40 degrees Celsius and normal saline using the site <https://www.randomizer.at/>.

Participants/Inclusion and exclusion criteria

Inclusion criteria were age between 19-63, surgery needed to general anesthesia and lack of cold or throat infections. Exclusion criteria: surgery on the neck and chest, clear hoarseness, previous laryngeal surgery, need for an abnormal position during the operation

Intervention groups

In the control group (n=29) the normal endotracheal tube will not be heated and in the intervention group (n=29) the endotracheal tube will be heated with normal saline 40 ° C. Intervention is not medication and is related to equipment.

Main outcome variables

Sore throat, hoarseness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110213005822N4**

Registration date: **2021-03-01, 1399/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-01, 1399/12/11**

Update count: **0**

Registration date

2021-03-01, 1399/12/11

Registrant information

Name

Valiollah Hassani

Name of organization / entity

Department of Anesthesiology, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-14, 1399/02/25

Expected recruitment end date

2021-06-26, 1400/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of heating the tip of the endotracheal tube with warm normal saline before intubation in decreasing the prevalence of hoarseness and sore throat after removal of the tube

Public title
The effect of heating the tip of the endotracheal tube on hoarseness and sore throat

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 19-63 Surgery needed to general anesthesia Lack of cold or throat infections Satisfaction to participate in the study
Exclusion criteria:
 Surgery on the neck and chest Clear hoarseness Previous laryngeal surgery Need for an abnormal position during the operation

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients were randomly divided into two groups of heated endotracheal tube with normal saline 40 degrees Celsius and normal saline using the site <https://www.randomizer.at/>.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients were unaware of being in the intervention groups and remained blind until the end of the study because they are anesthetized , and the statistical analyzer also received the data as a code, not the actual grouping, such as group A for intervention and B for control.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences., next to Milad tower., Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-05-09, 1399/02/20

Ethics committee reference number
IR.IUMS.FMD.REC.1399.113

Health conditions studied

1

Description of health condition studied

Sore throat

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes

1

Description

Sore throat

Timepoint

20 minutes and 24 hours after endotracheal tube removal

Method of measurement

Examination (Yes/no)

2

Description

Hoarseness

Timepoint

20 minutes and 24 hours after endotracheal tube removal

Method of measurement

Examination (Yes/no)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After general anesthesia, in the intervention group (n = 29), the endotracheal tube heated with normal saline 40 ° C (product of Supa

company) will be intubated.

Category

Prevention

2

Description

Control group: After general anesthesia, in the control group (n = 29), the normal endotracheal tube (unheated) (product of Supa company) will be intubated.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Hospital

Full name of responsible person

Valiollah Hassani

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Niyayesh St, Sattarkhan St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Valiollah Hassani

Position

Professor of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available