

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of different cuff pressures of the tracheal tube on sore throat and hoarseness after general anesthesia

Protocol summary

Study aim

Comparison of the effects of various pressures of the cuff of the tracheal tube on sore throat and voice violence after general anesthesia

Design

Clinical trials without control group , with parallel groups, one-way blind, random allocation

Settings and conduct

In this clinical trial, the number of patients based on the sample size that was placed in the Gonabad Hospital in 2018-2019 under a general anesthetic under identical conditions was randomly assigned (randomly) into three groups A (cuff pressure of 23 to 20 cm Water), group B (cuff pressure 26-23 cm water) and group c (30-26 cm water). All patients will undergo anesthesia in the same way. After the patients get the recovery clearance criteria, they are transferred to the department, and the presence and severity of sore throats and post-surgical violence are fixed by one person (nurse section) who are not aware of the grouping of samples at 1, 12 and It will be measured 24 hours after the patient's intelligence and marked in the checklist of the researcher.

Participants/Inclusion and exclusion criteria

1. Patient's complete satisfaction 2. patients under general anesthesia without surgery on the mouth, head and neck. 3. No problems such as airway anomalies , sore throats or violent voice (with the approval of the ENT specialist) 4. 1 or 2 class ASA 5. No Smoking 6.Age is16-65 years old 7. No respiratory and laryngeal diseases 8. Duration of anesthesia between half and two hours 9. Non-use of medicines affecting sore throat and voice violence

Intervention groups

In three groups, the effect of different pressures of the cuff of the tracheal tube on the sore throat and sound violence will be investigated

Main outcome variables

Prevention of two complications of sore throat and voice violence in patients undergoing general anesthesia with

a tracheal tube

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042616N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Zahra Sadeghi noghabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5725 2918

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of different cuff pressures of the tracheal tube on sore throat and hoarseness after general anesthesia

Public title

Comparison of the effect of different cuff pressures of the tracheal tube on sore throat and hoarseness after general anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's complete satisfaction patients under general anesthesia without surgery on the mouth, head and neck
No problems such as airway anomalies , sore throat or violent voice (with the approval of the ENT specialist)
Class 1 or 2 anesthetics according to the ASA No Smoking Age is 16-65 years old No respiratory and laryngeal diseases Duration of anesthesia between half and two hours Non-use of medicines affecting sore throat and voice violence

Exclusion criteria:

difficult intubation (more than once trying to intubate)
Need for mechanical ventilation after surgery in the intensive care unit

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

in the form of Permuted block randomization , individuals will be placed in three groups A (cuff pressure 24-20 cm water), group B (cuff pressure 29-25 cm water) and group C (30-34 cm water).

Blinding (investigator's opinion)

Single blinded

Blinding description

Health care personnel (nurses) that responsible for patient care, as well as sore throat and voice assessment after anesthesia, will not be aware of the groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad university of Medical Sciences

Street address

No.5, Taleghani , 12 Taleghani

City

Gonabad

Province

Razavi Khorasan

Postal code

9691639663

Approval date

2019-01-07, 1397/10/17

Ethics committee reference number

IR.GMU.REC.1397.100

Health conditions studied

1

Description of health condition studied

sore throat and voice violence

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sore throat

Timepoint

1, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

2

Description

Degree of voice violence

Timepoint

1, 12 and 24 hours after surgery

Method of measurement

Researcher checklist made

Secondary outcomes

1

Description

Age

Timepoint

Beginning of study

Method of measurement

Researcher checklist made

2

Description

Sex

Timepoint

Beginning of study

Method of measurement

Researcher checklist made

3

Description

American Society of Anesthesiologists

Timepoint

Beginning of study

Method of measurement

Researcher checklist made

4

Description

Weight

Timepoint

Beginning of study

Method of measurement

Researcher checklist made

5

Description

Intubation time

Timepoint

After intubation

Method of measurement

Researcher checklist made

6

Description

Duration of anesthesia

Timepoint

End of surgery

Method of measurement

Researcher checklist made

Intervention groups

1

Description

Intervention group A: Pressure the cuff tube between 20 to 24 cm of water

Category

Prevention

2

Description

Intervention group B: Pressure the cuff of the trachea tube between 25 to 29 centimeters of water

Category

Prevention

3

Description

Intervention group C: Pressure the cuff of the trachea tube between 30 to 34 centimeters of water

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohloul hospital

Full name of responsible person

Zahra sadeghi noghabi

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Saadi Ave , Vahdat Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Ali sagadi

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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

Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Zahra sadeghi noghabi
Position
Student
Latest degree
A Level or less
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)

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