Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 51 5725 2918

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sadeghi.z.stu@gmu.ac.ir

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 is16-65 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
Bohlool hospital
Full name of responsible person
Zahra sadeghi noghabi
Street address
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
Street address
saadi Ave, Vahdat Blvd, Gonabad university of mddical sciences
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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