

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Investigating the effect of tracheal tube cuff pressure balancing in preventing sore throat and hoarseness in general anesthesia using nitrous oxide in surgery in supine and prone positions

Protocol summary

Study aim

Investigating the effect of tracheal tube cuff pressure balancing in preventing sore throat and hoarseness in general anesthesia using nitrous oxide in surgery in supine and prone positions

Design

The study will be double blind and clinical trial. 212 patients will be randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Candidates for general anesthesia in Valiasr hospital in Arak city are divided into 4 groups by simple randomization using the block method. The study is double-blind and blinding of the analyst and the outcome evaluator and the participant is done. All intubations will be performed by the anesthesia resident. Adjusting the tracheal tube cuff pressure will be done by supervisor. The follow-up of patients and recording of information and completion of the checklist will be done by resident.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30 to 60 years; no history of chronic use of painkillers; insensitivity to nitrous oxide; failure to perform laparoscopic surgery; absence of upper airway infection and colds; no need to use NG-tube during surgery and up to 24 hours after surgery; the duration of surgery should not be less than 60 minutes and not more than 120 minutes; consent to participate in the study. Exclusion criteria: the patient's lack of consent to continue participating in the study; observing blood during suction when removing the tracheal tube; for any reason, we have to perform laryngoscopy twice on the patient.

Intervention groups

Patients will be divided into four groups. In the intervention groups, oxygen and N₂O with a concentration of 50:50 are prescribed in prone and supine positions. In the control group, oxygen and air are

prescribed as 50:50 with two positions, prone and supine.

Main outcome variables

Sore throat, voice harshness, average propofol consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N187**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of tracheal tube cuff pressure balancing in preventing sore throat and hoarseness in general anesthesia using nitrous oxide in surgery in supine and prone positions

Public title
Investigating the effect of tracheal tube cuff pressure balancing in preventing sore throat and hoarseness in general anesthesia using nitrous oxide in surgery in supine and prone positions

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 30 to 60 years ASA class I and II No history of sore throat before surgery No history of drug use No history of chronic use of painkillers Insensitivity to nitrous oxide Failure to perform laparoscopic surgery Absence of upper airway infection and colds Absence of malampati more than 2 No need to use NG-tube during surgery and up to 24 hours after surgery The duration of surgery should not be less than 60 minutes and not more than 120 minutes Consent to participate in the study
Exclusion criteria:
The patient's lack of consent to continue participating in the study Observing blood during suction when removing the tracheal tube For any reason, we have to perform laryngoscopy twice on the patient.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **212**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the specialized assistant does not know about the prescribed drugs, and the follow-up of the patients is with the anesthesiology resident, and the analyst does not know about the grouping, and as a result, the study will be double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

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

Street address
Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2023-06-06, 1402/03/16

Ethics committee reference number
IR.ARAKMU.REC.1402.064

Health conditions studied

1

Description of health condition studied
General anesthesia

ICD-10 code
Y48.2

ICD-10 code description
Other and unspecified general anaesthetics

Primary outcomes

1

Description
Sore throat

Timepoint
Recovery and 2, 4, 8, 12 and 24 hours after the operation

Method of measurement
Pain Visual Analog scale

2

Description

Voice hoarseness

Timepoint

Recovery and 2, 4, 8, 12 and 24 hours after the operation

Method of measurement

Physical examination

3

Description

Mean propofol consumption

Timepoint

End of study

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The same tracheal tube from the same brand (flexicare, made in England) is used with a low pressure cuff (tracheal tube size 7-5/7 for women and 5/7-8 tracheal tube for men) Tracheal tube cuff using Ambu device cuff pressure gage and the water is inflated to a pressure of 25 cm, so that there is no audible air leakage at the maximum inspiratory pressure. The method of induction of general anesthesia is the same in all four groups, and isoflurane (0.5-1%) and Pofol infusion at a dose of 50-100 micrograms per kg per minute, and itracurium and fentanyl are prescribed at appropriate times, also in the position group. Supine oxygen and N2O are prescribed with a concentration of 50:50.

Category

Treatment - Devices

2

Description

Intervention group2 : The same tracheal tube from the same brand (flexicare, made in England) is used with a low pressure cuff (tracheal tube size 7-5/7 for women and 5/7-8 tracheal tube for men) Tracheal tube cuff using Ambu device cuff pressure gage and the water is inflated to a pressure of 25 cm, so that there is no audible air leakage at the maximum inspiratory pressure. The method of induction of general anesthesia is the same in all four groups, and isoflurane (0.5-1%) and Pofol infusion at a dose of 50-100 micrograms per kg per minute, and itracurium and fentanyl are prescribed at appropriate times, also in the position group. Perone oxygen and N2O are prescribed with a concentration of 50:50.

Category

Treatment - Devices

3

Description

control group1: The same tracheal tube from the same brand (flexicare, made in England) is used with a low pressure cuff (tracheal tube size 7-5/7 for women and 5/7-8 tracheal tube for men) Tracheal tube cuff using Ambu device cuff pressure gage and the water is inflated to a pressure of 25 cm, so that there is no audible air leakage at the maximum inspiratory pressure. The method of induction of general anesthesia is the same in all four groups, and isoflurane (0.5-1%) and Pofol infusion at a dose of 50-100 micrograms per kg per minute, and itracurium and fentanyl are prescribed in appropriate timings as anesthesia maintenance. In the supine position group Oxygen and air are prescribed as 50:50.

Category

Treatment - Devices

4

Description

control group 2: The same tracheal tube from the same brand (flexicare, made in England) is used with a low pressure cuff (tracheal tube size 7-5/7 for women and 5/7-8 tracheal tube for men) Tracheal tube cuff using Ambu device cuff pressure gage and the water is inflated to a pressure of 25 cm, so that there is no audible air leakage at the maximum inspiratory pressure. The method of induction of general anesthesia is the same in all four groups, and isoflurane (0.5-1%) and Pofol infusion at a dose of 50-100 micrograms per kg per minute, and itracurium and fentanyl are prescribed at appropriate times, also in the position group. Peron oxygen and air are prescribed as 50:50.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Esmaeel Moshiri

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Sponsors / Funding sources

Sponsor**Name of organization / entity**

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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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