

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Postoperative sore throat and the pressure of endotracheal tube cuff filled with air or saline following tracheal intubation in different body positions

Protocol summary

Study aim

Assessment of endotracheal tube cuff pressure filled by air versus saline and postoperative sore throat in patients undergoing abdominal and orthopedic surgery with lateral position

Design

A double-blinded, parallel-group clinical trial with random sampling and allocation in intervention and control group

Settings and conduct

An available double-blinded sampling will be conducted on patients referred to the central operating room of Qaem Hospital, Mashhad. They will be all candidates of 1 to 2-hour abdominal or orthopedic surgery in the lateral position with GA. Neither analyst nor participant will be informed about group allocation. After the intubation in the supine position, the endotracheal tube cuff is filled with saline in intervention and air in control group, until a pressure of 15 cm H₂O is reached. Checklist variables are recorded during the surgery (VBM cuff pressure gauge is used in the control group and the transducer and monitoring device of the VECTRA Company is employed in intervention group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of a previous acute or chronic throat, jaw and larynx illness or surgery; Being alert; Not being intubated an endotracheal tube initially; Being able to speak Persian; Having lateral position during the surgery; Scheduled to undergo abdominal and orthopedic Surgery; No history of drug allergy affecting general anesthesia; BMI = 18.5-25 kg/m² and Exclusion criteria: Mallampati score 3 & 4; ASA more than 3; Duration of intubation more than 20 seconds; The need for steroidal anti-inflammatory and NSAIDs up to 24 hours after surgery

Intervention groups

After the intubation in the supine position, the endotracheal tube cuff is filled with saline in intervention

and air in control group respectively, until a pressure of 15 cm H₂O is reached.

Main outcome variables

Endotracheal tube cuff pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160516027925N3**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Amir Zoka

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3822 4395

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zokaa921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Postoperative sore throat and the pressure of endotracheal tube cuff filled with air or saline following tracheal intubation in different body positions

Public title
Postoperative sore throat and the pressure of endotracheal tube cuff

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
No history of a previous acute or chronic throat, jaw and larynx illness or surgery Being alert Not being intubated an endotracheal tube initially Being able to speak Persian Having lateral position during the surgery Scheduled to undergo abdominal and orthopedic Surgery No history of drug allergy affecting general anesthesia BMI = 18.5-25 kg/m²
Exclusion criteria:
mallampati score 3&4 ASA more than 3 Duration of intubation more than 20 seconds The need for steroidal anti-inflammatory and non-steroidal anti-inflammatory drugs up to 24 hours after surgery

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to the control or intervention group by drawing a random number out of a bag

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will not be informed about which group they are in. Also, the data analyst will be blind to which group the participants are assigned

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Administration Center(Qoreishi Building), Daneshgah St, Mashhad, Iran

City

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Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2018-01-31, 1396/11/11

Ethics committee reference number

IR.MUMS.fm.REC.1396.678

Health conditions studied

1

Description of health condition studied

Postoperative cuff pressure after the operation of patients undergoing abdominal and orthopedic surgery with lateral position

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Endotracheal tube cuff pressure

Timepoint

After intubation, before change the position, after change the position, before extubation

Method of measurement

Pressure Gauges endotracheal tube cuff pressure &

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The cuff of the endotracheal tube of the intervention group is filled in with water after the intubation in the supine position until a pressure of 15 cm H₂O is reached.

Category

Treatment - Devices

2

Description

Control group: The cuff of the endotracheal tube of the Control group is filled in with air after the intubation in the supine position until a pressure of 15 cm H₂o is reached.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem hospital

Full name of responsible person

Mohsen Sabermoghaddam

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Ahmadabad Blvd, Mashhad, Razavi Khorasan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

Mashhad 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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Amir Zoka

Position

Academic instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All de-identified individual participant data will be shared. Both of the entire study protocol and informed consent of the participants in the study are shared too.

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Given the patient's satisfaction to participate in this study, the data should only be used for similar studies

From where data/document is obtainable

Email to the authors Sabermoghaddamm@mums.ac.ir
Zokaa1@thums.ac.ir

What processes are involved for a request to access data/document

After the email, the request will be made available to the authors to reach the requesting person within a maximum of one month if the conditions are confirmed.

Comments