Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Email address

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

Mashhad

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
Street address
Ahmadabad Blvd, Mashhad, Razavi Khorasan Province
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Sponsors / Funding sources

1

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Name of organization / entity
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sabermoghaddamm@mums.ac.ir
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
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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