Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the Effect of Endotracheal Tube Cuff Pressure on Sore Throat, Hoarseness and Cough in Patients with Coronary Artery Bypass Surgery

Protocol summary

Summary

1- Objectives : The aim of this study was to investigate the effect of endotracheal tube cuff pressure on sore throat, hoarseness and cough in patients with cardiac artery bypass surgery. 2- Design : This quasi-experimental clinical trial in 72 patients undergoing coronary artery bypass graft surgery in Afshar Hospital of Yazd in 2016 . 3- Setting and Conduct : The sampling easy and assigned to two experimental and control groups was carried out. 4- Intervention : In the control group and by the anesthesiologist routine tracheal cuff pressure was adjusted . In the experimental group , after being intubated by standard manometer, pressure cuff at a rate of 2 ± 22 cm of water was regulated and controlled. Data hoarseness, sore throat and cough are 2 , 6 , 12 and 24 hours in both groups by measuring scales , collecting and using statistical software SPSS 20 , were analyzed. 5- Participants including major eligibility criteria : Inclusion criteria were: age between 18 - 75 years ; A patient for surgery was selected for the first time ; They are between 1 - 4 hours and the duration of intubation during surgery less than 24 hours to prevent the impact of other detrimental factors ; And those with a history of sore throat and pharyngitis to 4 weeks prior to surgery ; And a history of respiratory problems ; Addictions, smoking and drug allergy ; As well as patients in the study were throat pain unbearable or housing request ; Longer than 30 seconds for intubation needed ; Or during the study needs to be repeated or replacing the pipes or more than 24 hours under ventilation were excluded from the study. 6- main outcome measures) (variables) : Sore throat, Hoarseness and Cough.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042633657N1**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Mohammad Hassan Mondegari Bamakan

Name of organization / entity

School of Nursing & Midwifery, Shahid Sadughi University of Medical Science, Yazd

Country

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Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery Yazd

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effect of Endotracheal Tube Cuff Pressure on Sore Throat, Hoarseness and Cough in Patients with Coronary Artery Bypass Surgery

Public title
Investigating the Effect of Endotracheal Tube Cuff Pressure on Sore Throat, Hoarseness and Cough
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria were: age between 18 - 75 years ; A patient for surgery was selected for the first time ; They are between 1- 4 hours ; And the duration of Intubation during surgery less than 24 hours to prevent the impact of other detrimental factors ; Risks of surgery at level 1 and 2 ; and the tracheal tube according to the sex of the patient ; As well as not having a history of head and neck surgery ; Anesthesia, medications used was similar adjustments ventilator for all patients ; And those with a history of sore throat and pharyngitis to 4 weeks prior to surgery ; And a history of respiratory problems ; Addictions, smoking and drug allergy ; As well as patients in the study were throat pain unbearable or housing request ; Inotrope drugs or vasodilator in the intensive care unit received more than 10 microns ; Longer than 30 seconds for intubation needed ; Or during the study needs to be repeated or replacing the pipes or more than 24 hours under ventilation were excluded from the study.
Age
From **77 years** old to **20 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Shahid Sadughi University Of Medical Siences
Street address
In Front of the Infertility Center, Bu Ali street , Safaieh
City
Yazd
Postal code
Approval date
2016-06-26, 1395/04/06
Ethics committee reference number
ir.ssu.rec.1395.030

Health conditions studied

1

Description of health condition studied
Angina pectoris
ICD-10 code
I20
ICD-10 code description
Angina pectoris

Primary outcomes

1

Description
Sore Throat
Timepoint
2 hours, 6 hours, 12 and 24 hours after Extubation
Method of measurement
To search for pain from zero to 3 ; (Zero score : without sore throat ; a score of 1 : Mild sore throat (only if the person to ask) ; score 2 : moderate sore throat (pharyngitis expressed by the patient) ; grade 3 : severe sore throat (change in volume with sore throat))

2

Description
Hoarseness
Timepoint
2 hours , 6 hours , 12 and 24 hours after Extubation
Method of measurement
As well as a change in sound quality was defined Hoarseness and its severity was determined by 4 degrees from zero to three (zero score : without hoarseness ; 1 score : violence that only by patient reported noise during the interview ; the score 2 : clear sound but mild violence ; Score 3 : violence clear sound and sharp) and transfer the patient to the intensive care unit after surgery

3

Description
Cough
Timepoint
2 hours , 6 hours , 12 and 24 hours after Extubation
Method of measurement
To measure any cough or mild and the extreme of the

scale was 0 to 4 (zero score: without coughing ; rare 1: score ; score 2 : casual less than an hour ; score 3 : repeated one or more times an hour ; the score 4 : almost unchanged)

Secondary outcomes

empty

Intervention groups

1

Description

In the Intervention group, after intubated by an anesthesiologist (with more work experience of 5 years) (using the touch pad cuff), by trained nurses with listed for the control group (during the first 10 minutes of anesthesia) was set at a rate of 22 ± 2 cm of water (in the first endotracheal tube cuff pressure measurement, if the level it was different with the rate of 22 ± 2, first, the correction was recorded). At the time of admission to intensive care unit and in the interval of 2 hours, 4 hours and 6 hours after control and this amount has been set. Then, after removing the tube samples both within 2 hours, 6 hours, 12 and 24 hours later, by measure sore throat, cough and hoarseness, in terms of throat pain, cough and respiratory violence are investigated and recorded.

Category

Treatment - Drugs

2

Description

In order to collect data, demographic data and medical records endotracheal tube cuff pressure was used. In the Control group, patients with endotracheal tube cuff pressure by the anesthesiologist (with more work experience of 5 years) with a 10 cc syringe using the touch pad cuff; during the first 10 minutes of anesthesia, time of admission to the intensive care unit and then in a period of 2 hours, 4 hours and 6 hours later using a handheld German construction company pressure measurement range between zero and 120 cm of water, was measured and recorded. In this study, all patients participating in the study tracheal tube made of PVC with a life company (Intellectuals Health) brand was used, but lead. So that for women size 7 - 7.5 and for men Size 8 - 8.5 Used .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital

Full name of responsible person

Bashardoost And Andisheh ICU

Street address

Afshar Hospital , Gomhuri BLV, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Sadughi University of Medical Sciences

Full name of responsible person

Ali Akbar Vaezi

Street address

In Front of the Infertility Center, Bu Ali street , Safaieh

City

yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahid Sadughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd School of Nursing and Midwifery

Full name of responsible person

Mohammad Hassan Mondegari Bamakan

Position

Msn in Critical Care Nursing

Other areas of specialty/work

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Full name of responsible person
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Position
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Other areas of specialty/work

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Full name of responsible person
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Position
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty