Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparing the effect of two endotracheal tube cuff inflation methods on the air leackage and atelectasia frequency in undergoing CABG.

Protocol summary

Summary

This research is a randomized controlled clinical trial. Statistical population of this research includes 220 male and female patients who are referred to Mazandaran Heart Center for CABG surgery. Samples are placed randomly in 2 groups named control and case by block randomized permutation method. intervention group are examined with volume-time curve method and control group are examined using auscultation (without any sound of air leakage) method for air leakage and atelectasis frequency . Inclusion criteria: age above 18, normal BMI (18.5-24.9), intubation through endotracheal tube (orotrachea , under mechanical ventilation and CABG surgery, FEV1/FVC > 0.7 (based on spirometery), absence of acute or chronic pulmonary disease , heart failure , immunodeficiency , COPD, asthma , severe valve failure , larynx disease or laryngeal anomalies. Exclusion criteria: difficult intubation in 2 or more than 2 try, reoperation due to critical condition after surgery (more than 1000 cc drainage ,heart tamponade) . History of pulmonary diseases in last 2 months. air leakage and cuff pressure assessment leads to assessment of microaspiration frequency due to air leakage and finally assessment of frequency of atelectasis. In this research we compare 2 endotracheal cuff tube inflation methods: 1-"volume-time curve" method -2- "inflating the endotracheal tube cuff without any audible sound of air leakage" method on atelectasis frequency in patients under CABG surgery upon arrival at ICUOH and after the surgery at 35.5 and 37 Celsius degrees. Diagnosis of atelectasis is done after extubation of patients through CXR, under two radiologists' Diagnosis. Data Collection tool is a checklist including heart demographic information of patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091319677N4**
Registration date: **2017-10-15, 1396/07/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name
Ravanbakhsh Esmaeili
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Mazandaran University of Medical Sciences

Expected recruitment start date

2017-09-16, 1396/06/25

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of two endotracheal tube cuff inflation methods on the air leackage and atelectasia

frequency in undergoing CABG.

Public title
The Comparison of two methods of endotracheal tube cuff pressure regulation on atelectasis in patients under mechanical ventilation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age above 18 ; normal BMI (18.5-24.9) ; intubated through endotracheal tube (orotracheal) ;patients under mechanical ventilation and open heart surgery and CABG; FEV1/FVC > 0.7 (based on spirometery);chest x ray (based on radiologist's diagnosis) and history and examination(by Heart anesthetist)not to mention to acute or chronic pulmonary disease; heart failure ; immunodeficiency ;absence of chronic pulmonary disease(COPD) ; asthma ;patients with severe valve failure ; laryngeal disease or laryngeal anomalies. Exclusion criteria: Patients with difficult intubation in 2 or more than 2 try ; reoperation due to post surgery critical condition (more than 1000 cc drainage ; heart tamponade) ; history of Pulmonary diseases in last 2 months.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **220**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Mazandaran University of Medical
Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.
City
Sari
Postal code
13445-48167
Approval date
2017-09-13, 1396/06/22
Ethics committee reference number
IR.mazums.REC.96.91884

Health conditions studied

1

Description of health condition studied
atelectasis
ICD-10 code
J98.1
ICD-10 code description
Pulmonary collapse

Primary outcomes

1

Description
air leackage and atelectasis
Timepoint
24 hours after the intervention
Method of measurement
auscultation

Secondary outcomes

1

Description
endotracheal cuff pressure with volume-time curve technique
Timepoint
after admition to ICU and hemodynamic stabilization and temperture 35.5 , 37 with 20 minute interval
Method of measurement
Pressure gauge manometer

2

Description
endotracheal cuff pressure without any audible sound of air leakkage technique
Timepoint
after admition to ICU and hemodynamic stabilization and temperture 35.5 , 37 with 20 minute interval
Method of measurement
Pressure gauge manometer

3

Description
Arterial oxygen pressure
Timepoint
20 minute after extubation
Method of measurement

Arterial blood gas test(ABG)

4

Description
cross clamp time
Timepoint
during surgery
Method of measurement
Clock Gauge

5

Description
body tempreture
Timepoint
after admition to ICU and 3 times after surgery in 20 minute intervals
Method of measurement
termometer

Intervention groups

1

Description
Intervention group:after transferring the patient from operation room to ICU ,after stabilization of patient's hemodynamic condition ,air leakage from endotracheal cuff will be examined and resolved by volume- time curve in 3 stages (upon arrival,35.5 and 37 centigrade).20 minutes after patient extubation ,atelectasis will be recognized by CXR.
Category
Prevention

2

Description
Control group:Intervention group:after transferring the patient from operation room to ICU ,after stabilization of patient's hemodynamic condition ,air leakage from endotracheal cuff will be examined and resolved by auscultation method - without any audible sound of air leakage in 3 stages (upon arrival,35.5 and 37 centigrades).20 minutes after patient extubation ,atelectasis will be recognized by CXR.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mazandaran Heart Center Hospital
Full name of responsible person
Saeed Jafari
Street address
Mazandaran Heart Center Hhospital, Artesh blvd, Sari, Mazandaran
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayeti
Street address
Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street, Moalem Square, Sari, Iran
City
Sari
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 Mazandaran 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
Mazandaran University of Medical Sciences - School of Nursing and Midwifery Nusseibeh
Full name of responsible person
Saeed Jafari
Position
Student of Master of Critical Care Nurses
Other areas of specialty/work
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Person responsible for scientific inquiries

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Assistant Professor

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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