

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparing the effect of two endotracheal tube cuff inflation methods on the air leakage 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 spirometry), 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 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 Esmaili

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3336 7345

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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 leakage 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 spirometry);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 leakage 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 admission to ICU and hemodynamic stabilization and temperature 35.5 , 37 with 20 minute interval

#### Method of measurement

Pressure gauge manometer

### 2

#### Description

endotracheal cuff pressure without any audible sound of air leakage technique

#### Timepoint

after admission to ICU and hemodynamic stabilization and temperature 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 temperature

##### **Timepoint**

after admission to ICU and 3 times after surgery in 20 minute intervals

##### **Method of measurement**

thermometer

## **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 Hospital, 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**

###### **Street address**

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## Person responsible for scientific inquiries

### Contact

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**Position**

Assistant Professor

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## Person responsible for updating data

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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*