Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Intraoperative lung protective ventilation with conventional ventilation on postoperative pulmonary complications in CABG

Protocol summary

Summary

In this study, we attempt to compare effects of lung protective ventilation with the current standard method on the incidence of pulmonary complications after surgery in long-term coronary artery bypass grafting surgeries (CABG) (over 120 minutes). The study is a double-blind randomized clinical trial in the Moheb hospital from March 2014 until March 2015. Inclusion criteria are patients candidate for CABG operation under general anesthesia without any specific medical disorder. Exclusion criteria are Hemoglobin < 10; Albumin <3 g/dl; Continuous hemodynamic unstability; Resistant shock; Prediction of long term mechanical ventilation after the surgery; non-early extubation (more than 6 hours after end of the surgery). Patients with inclusion criteria are randomized with quadric block method into two groups of 32 people with specific code, as Conventional ventilation group with tidal volume 9 ml per kg and positive end-expiratory pressure 0 and lung protective ventilation group with tidal volume 6 mL per kg and positive end-expiratory pressure 10. In the intervention group, the recruitment maneuver is performed after induction of anesthesia. Dyspnea, cough, sputum and chest and abdominal pain will be measured according to the VAS scale, also Postoperative pulmonary complications (PPC), as well as modified Clinical Pulmonary Infection Score (mCPIS) before and in the first 24 hours after the operation. IL-6 levels is measured before, exactly after and also after 24 hours of the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040115774N3**
Registration date: **2015-06-25, 1394/04/04**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-06-25, 1394/04/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date

2014-03-15, 1392/12/24

Expected recruitment end date

2015-03-15, 1393/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Intraoperative lung protective ventilation with conventional ventilation on postoperative pulmonary complications in CABG

Public title

Comparison of Intraoperative lung protective ventilation

with conventional ventilation on postoperative pulmonary complications in CABG

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria are patients candidate for CABG operation under general anesthesia; Patient's satisfaction with participating in the study and doing the respiratory examinations; BMI< 30 kg/m² age more than 18 and under 70; No pregnancy; No emergent surgery; No previous respiratory system surgery; No history of chronic obstructive pulmonary disease; No sleep disorder; No History of immune suppressant therapy(chemotherapy or radiotherapy) in the last 2 months; No acute respiratory damage or acute respiratory distress syndrome; No repeated treatment with systemic corticosteroid; No liver or neuromuscular disorders; No alcohol or substance abuse; No anesthetic drugs allergy; No cigarette smoking (less than 10 pack/year). Exclusion criteria are Hemoglobin < 10; Albumin <3 g/dl; Continuous hemodynamic unstability; Resistant shock; Prediction of long term mechanical ventilation after the surgery; non-early extubation (more than 6 hours after end of the surgery).

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of Iran University of Medical Sciences

Street address
West Hemmat Highway

City
Tehran

Postal code

Approval date
2014-05-12, 1393/02/22

Ethics committee reference number
774/105/93ر

Health conditions studied

1

Description of health condition studied
postoperation complications of respiratory system

ICD-10 code
J95.9

ICD-10 code description
Postprocedural respiratory disorder, unspecified

Primary outcomes

1

Description
postoperative pulmonary complications

Timepoint
after the surgery

Method of measurement
3 or more of these six postoperative pulmonary complications: cough, discharge increase, dyspnea, chest pain, temperature more than 38C, heart rate >100 per minute

Secondary outcomes

1

Description
Modified Clinical Pulmonary Infection Score

Timepoint
After the surgery

Method of measurement
According to mentioned parameteres : Glasco scale, Mean Arterial Pressure, need for vasopressor to support cardiovascular system,Serum Aspartate Transaminase Level, Liver bilirubin, Protrombin time and platlets, coagulation factors and serum creatine

2

Description
IL-6 levels

Timepoint
before, exactly after and also after 24 hours of the surgery.

Method of measurement
laboratory

Intervention groups

1

Description

The control group receives common ventilation with tidal volume= 9 ml/kg and respiratory rate adjustment with EtCO2= 30-35 cmH20 and PEEP=0.

Category

Treatment - Devices

2

Description

Intervention group recieves lung protective ventilation with tidal volume=6 ml/kg and respiratory rate adjustment with EtCo2=30-35 cmH2o and PEEP=10 cmH2o. In the intervention group, the recruitment maneuver is performed after induction of anesthesia.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Moheb Hospital

Full name of responsible person

Dr. Mohammad Mahdi Zamani

Street address

Lida st., above vanak field, Valiasr st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran university of medical sciences

Full name of responsible person

Dr.Morteza Naserbakht

Street address

floor 5, central building, junction of Shahid Hemmat & Shahid Chamran Expressways, Tehran

City

Tehran

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, Iran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Anesthesiology and Critical Care, Iran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Ghodrati

Position

Associated Professor/Attending Physician

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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