Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Comparison between continuous lung ventilation at low minute volume and non-ventilation during pumping in oxygenation and extubation in patients undergoing coronary bypass surgery

Protocol summary

Summary

Objective: Comparison between continuous lung ventilation at low minute volume and non-ventilation during pumping in oxygenation and extubation in patients undergoing coronary bypass surgery. Design: Randomized, single blind (researchers were unaware), Target sample size: 30 People from patients undergoing coronary bypass surgery. The main inclusion criteria: Male and female candidates for elective coronary artery bypass surgery; Consent to participate in the study; The age range of 40-75 years; Body mass index (BMI)) less than 30. The main exclusion criteria: Underlying lung disease; Previous history of diabetes; Pulmonary blood pressure; Grade 2 (or higher) diastolic dysfunction; previous history of surgery or CABG surgery; Ejection fraction (EF) less than 30%; Pumping time more than 2 hours; Long ventricular fibrillation or prolonged heart massage during surgery; Other factors causing prolonged ventilation. Intervention group: Patients with continuous ventilation of the lungs with low minute volume, with a tidal volume of 4 ml/ kg and a respiratory rate of 12 per minute during cardiopulmonary bypass pump. Control group: Patients without ventilation, after connecting to cardiopulmonary bypass pump, oxygen and ventilation are disconnected and oxygenation of the patient's blood occurs through a bypass pump (CPB). Primary outcome measure: Oxygen Pressure in arterial blood and Fraction of Inspired Oxygen, Before induction and after intubation and before starting the pomp, during and after removal the pomp at the end of surgery, by Arterial blood test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042513159N4**

Registration date: **2014-05-17, 1393/02/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-17, 1393/02/27

Registrant information

Name

Shima Sheybani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3764 7230

Email address

sheybanish@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-06-01, 1393/03/11

Expected recruitment end date

2015-06-01, 1394/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between continuous lung ventilation at low minute volume and non-ventilation during pumping in

oxygenation and extubation in patients undergoing coronary bypass surgery

Public title
Improvement in Pulmonary parameters in patients during and after coronary bypass surgery
Purpose
Treatment
Inclusion/Exclusion criteria
The main inclusion criteria: Male and female candidates for elective coronary artery bypass surgery; Consent to participate in the study; The age range of 40-75 years; Body mass index (BMI)) less than 30. The main exclusion criteria: Underlying lung disease; Previous history of diabetes; Pulmonary blood pressure; Grade 2 (or higher) diastolic dysfunction; previous history of surgery or CABG surgery; Ejection fraction (EF) less than 30%; Pumping time more than 2 hours; Long ventricular fibrillation or prolonged heart massage during surgery; Other factors causing prolonged ventilation.
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Male and female candidates for undergone elective coronary bypass surgery on- pump, are divided into two groups of 15, based on a random table. Extubation in patients is scheduled by a nurse who is unaware about research.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad
City
Mashhad
Postal code
Approval date
2013-11-20, 1392/08/29
Ethics committee reference number
920273

Health conditions studied

1

Description of health condition studied
Pulmonary heart disease
ICD-10 code
I27.9
ICD-10 code description
Pulmonary heart disease, unspecified

Primary outcomes

1

Description
Oxygen Pressure in arterial blood
Timepoint
Before, During and after anesthesia
Method of measurement
Arterial blood test

2

Description
Fraction of Inspired Oxygen
Timepoint
Before, during and after anesthesia
Method of measurement
Arterial blood test

Secondary outcomes

1

Description
Point atelectasis
Timepoint
In ICU after intervention
Method of measurement
Chest radiograph

Intervention groups

1

Description
Intervention group: patients with continuous ventilation of the lungs with low minute volume, with a tidal volume of 4 ml/ kg and a respiratory rate of 12 per minute during cardiopulmonary bypass pump
Category

Treatment - Other

2

Description
Control group: Patients without ventilation, after connecting to cardiopulmonary bypass pump, oxygen and ventilation are disconnected and oxygenation of the patient's blood occurs through a bypass pump (CPB).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Shima Sheybani
Street address
Ghaem hospital, Ahmadabad Avenue, Mashhad
City
Mashhad

2

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Shima Sheybani
Street address
Shariati hospital, Three ways of Torghabe-Shandiz, Zaferanieh Blv, Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad
City
Mashhad
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, Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Shima Sheybani
Position
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Person responsible for scientific inquiries

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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