Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Low Tidal Volume Ventilation during Cardiopulmonary Bypass on Pulmonary Function after Cardiac Surgery

Protocol summary

Summary

Objective and Background: Postoperative pulmonary dysfunction is one of the most frequent complications after cardiac surgery that believed to result from the use of Cardiopulmonary bypass (CPB). In this study We investigated the effect of low tidal volume ventilation during Cardiopulmonary bypass on postoperative gas exchange and lung mechanics. Methods: This prospective randomized study included 100 patients undergoing elective coronary artery bypass graft. In 50 patients low tidal volume ventilation (T.V= 3 cc/kg , RR= 12/min , FIO2= 100% , PEEP= 5 cmH2o) was applied during CPB (group I). In the other 50 patients (group II) the lungs were open to the atmosphere without ventilation. Measurements were taken preoperatively, after CPB and before discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902283954N1**

Registration date: **2010-06-22, 1389/04/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-22, 1389/04/01

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2008-01-20, 1386/10/30

Expected recruitment end date

2009-03-20, 1387/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Low Tidal Volume Ventilation during Cardiopulmonary Bypass on Pulmonary Function after Cardiac Surgery

Public title

Ventilation during Cardiopulmonary Bypass

Purpose

Supportive

Inclusion/Exclusion criteria

Exclusion criteria were: ASA (American Society of Anesthesia) class> III, age> 70 years, poor left ventricular function (LVEF <40%), valvular heart disease, re operation, renal impairment and significant pulmonary disease as defined by preoperative FEV1 and FVC values less than 40% of predicted

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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 Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences

City

Hamedan

Postal code

Approval date

empty

Ethics committee reference number

16/70/2/37597/پ

Health conditions studied

1

Description of health condition studied

Genearl Anesthesia in Coronary Disease

ICD-10 code

I25.0

ICD-10 code description

Atherosclerotic cardiovascular disease, so described

Primary outcomes

1

Description

PaO2

Timepoint

after induction of anesthesia and endotracheal intubation and before sternotomy, 5 minutes , 2 and 4 hours after completion of CPB and after extubation in ICU

Method of measurement

mm/Hg

2

Description

FEV1

Timepoint

Time of extubation, preoperative and in the 5th postoperative day

Method of measurement

Liter

3

Description

FVC

Timepoint

Time of extubation, preoperative and in the 5th postoperative day

Method of measurement

Liter

Secondary outcomes

empty

Intervention groups

1

Description

Group I underwent low tidal volume ventilation (T.V= 3 cc/kg , RR= 12 / min , FIo2= 100% , PEEP= 5 cmH2o) during CPB period

Category

Treatment - Other

2

Description

Control group did not receive any ventilation during bypass

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Hospital

Full name of responsible person

Dr M.H. Bakhshaei

Street address

Ekbatan Hospital,

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research deputy of Hamedan University of Medical Sciences
Full name of responsible person
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Street address
Hamedan University of Medical Sciences
City
Hamedan

Grant name
پایان نامه های دانشجوئی
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Hamedan 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
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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