Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Effect of positive end expiratory pressure, five and ten cm H2O on the incidence of pulmonary complications in patients undergoing coronary artery bypass surgery.

Protocol summary

Summary

This study will investigate the effects two levels of positive end expiratory pressure (peep) on the incidence of pulmonary complications in patients undergoing coronary artery bypass surgery. After obtaining ethics committee approval, the study on 90 patients in the 30-80 age range who are candidates for coronary artery bypass surgery in Khorramabad Heart Hospital of Shahid Madani will be done. By consecutive non-probability sampling, patients will be randomly divided into two groups: control (n = 45) and intervention (n = 45). Meanwhile, the two groups are equal in age, sex, smoking history. and off-pump or on-pump. Inclusion criteria in the study are: 1- patients who are in the 30-80 age range. 2- Lack of ejection fraction (EF) less than 30% in preoperative angiography tab. 3- No history of chronic obstructive airway disease (COPD). 4-No previous history of open heart surgery. 5- No history of broken ribs and a chest tube investments. 6- Their operation is not urgent. 7- The level of consciousness (GCS) of patients is equivalent to fifteen. Exclusion criteria are : 1- Time of aortic clamping more than 100 minutes. 2- Time of heart - lung bypass more than 120 minutes. 3- Use of intra aortic balloon pump during and after surjery. 4- In case a patient needs ventilation protocol out of our research protocol should be excluded. 5- If a Sick has to be transferred to the operating room (OR) again. 6- If the patient is in intubation over 24 hours. Patients who are in control group from admission in the Intensive Care Unit to tracheal extubation time will receive a PEEP of 5 cm H2O. However, patients in intervention group, if their hemodynamic status is not impaired, they will receive for 4 hours an average of PEEP of 10 cm H2O and until extubation, PEEP of 10 cm H2O will receive. Then the two groups will be compared in terms of the incidence of atelectasis, pneumonia, pneumothorax, tracheal extubation time , chest drainage bottles and changes of parameters Pao2/Fio2, o2-sat and Paco2.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081714377N1**
Registration date: **2013-10-26, 1392/08/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-10-26, 1392/08/04

Registrant information

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Lorestan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Lorestan University of Medical Sciences

Expected recruitment start date

2013-08-01, 1392/05/10

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of positive end expiratory pressure, five and ten cm H2O on the incidence of pulmonary complications in patients undergoing coronary artery bypass surgery.

Public title
The effect of positive end expiratory pressure on the incidence of pulmonary complications.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria in the study are: 1- patients who are in the 30-80 age range. 2- Lack of ejection fraction (EF) less than 30% in preoperative angiography tab. 3- No history of chronic obstructive airway disease (COPD). 4-No previous history of open heart surgery. 5- No history of broken ribs and a chest tube investments. 6- Their operation is not urgent. 7- The level of consciousness (GCS) of patients is equivalent to fifteen. Exclusion criteria are : 1- Time of aortic clamping more than 100 minutes. 2- Time of heart - lung bypass more than 120 minutes. 3- Use of intra aortic balloon pump during and after surjery. 4- In case a patient needs ventilation protocol out of our research protocol should be excluded. 5- If a Sick has to be transferred to the operating room (OR) again. 6- If the patient is in intubation over 24 hours.
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients as stratified block are randomly divided into two groups of control and intervention. Because statistical specialists, patients and nurses are measuring variables of random assignment were not aware of the researcher is aware of the random assignment of subjects to be considered, therefore, double-blind study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences
Street address
km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences
City
Khorramabad
Postal code
Approval date
2013-07-27, 1392/05/05
Ethics committee reference number
200/90097/الف

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft
ICD-10 code
125.9
ICD-10 code description
Ischaemic heart disease (chronic) NOS

Primary outcomes

1

Description
Bottle chest drainage
Timepoint
When the chest tube take out
Method of measurement
According to the ranking of chest bottle

2

Description
Pao2/Fio2 ، o2-sat ، Paco2
Timepoint
Start entering the Intensive Care Unit, one hour, four hours, six hours later, just before tracheal extubation, one hour tafter the tracheal extubation , six hours after the tracheal extubation, and then twelve, twenty-four and forty-eight hours after tracheal extubation.
Method of measurement
By arterial blood gas analyzers

Secondary outcomes

1

Description
Pneumothorax
Timepoint
Early entry into the Intensive Care Unit , one hour after tracheal extubation , and 5-7 days after surgery.
Method of measurement
By chest radiography

2

Description
Pneumonia
Timepoint
Daily
Method of measurement
1-The new infiltration in chest x- ray، 2- leukocytosis over twelve thousand ، 3- fever over 38.3° C، 4- purulent sputum

3

Description
Atelectasis
Timepoint
Early entry into the Intensive Care Unit , one hour after tracheal extubation , and 5-7 days after surgery.
Method of measurement
By chest radiography

Intervention groups

1

Description
If the patient is in control group، from arrival to the Intensivel Care Unit to extubation time he will get the amount of 5 cm H2O of positive end expiratory pressure.
Category
Prevention

2

Description
Patients in intervention group، if hemodynamic status is not disrupted، will get for 4 hours an average of PEEP of 10 cm H2O and until extubation time، PEEP of 5 cm H2O will be received.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorramabad Hospital of Shahid Madani
Full name of responsible person
Behzad Moradi
Street address
Khorramabad Square Imam Hussein
City
Khorramabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Lorestan University of Medical Sciences
Full name of responsible person
Mohammad Hassan Kayydy
Street address
km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences
City
khoramabad
Grant name
2121
Grant code / Reference number
47352
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research Lorestan 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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Position
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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