Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Effect of Different Levels Positive End-Expiratory Pressure on the Incidence of Atelectasis After Heart Surgery

Protocol summary

Summary

This phase 2 Double blind, controlled randomized clinical trial aimed to evaluate the effect of different levels of positive end-expiratory pressure on atelectasis in patients after heart surgery. Following obtaining the permission from the ethics committee, 180 person are selected and classified as three different groups (n = 60). Patients are selected using convenience sampling method and randomly assigned in three groups including low level or control group (PEEP = 5), intermediate level (PEEP = 8), and high level (PEEP = 10). Inclusion criteria including: Patients candidate for non-emergency open heart surgery aged 18 until 65 years; No ejection fraction less than 30% in the angiography form, before surgery; No history of chronic airway obstruction disease and lung trauma; No history of open heart surgery or lung surgery; No history of rib fractures and chest tube insertion; No body mass index greater than 40. Exclusion criteria including: Arterial systolic pressure less than 90 mmHg despite of fluid intake; Arterial blood pH less than 7.30; arterial carbon dioxide pressure greater than 50 mmHg; arterial oxygen saturation less than 80% despite of supplemental oxygen intake; Aortic cross clamp time longer than 150 minutes; Cardiopulmonary bypass time longer than 240 minutes; Using intra aortic balloon pump (IABP) intraoperative and postoperative; Intubation over 24 hours; Also,the patient will be excluded from the study when he/she retransfers to the operating room or when he/she needs ventilator therapy protocols apart from of research protocols. Patients in the control group receive 5 cmH2O positive end expiratory pressure since entering the intensive care unit until the removal of the endotracheal tube. Patient in the intermediate and high levels will receive an average 8 and 10 cmH2O positive end expiratory pressure (PEEP) for 4 hours, (provided that the hemodynamic status is not disrupted). They will receive 5 cmH2O PEEP until the endotracheal tube removal. The intervention is stopped, in case of hypotension to 10 mmHg from the patient baseline blood pressure. Vital signs and arterial blood parameters will be evaluated before intervention, one and 4 hours after intervention inception and after extubation respectively. The incidence of atelectasis will be polled from the radiologists 2 hours after extubation and on the third day after surgery, according to the ray chest radiography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507307494N14**
Registration date: **2015-09-22, 1394/06/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-22, 1394/06/31

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Science

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date
2016-02-20, 1394/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Different Levels Positive End-Expiratory Pressure on the Incidence of Atelectasis After Heart Surgery

Public title
Effect of Different Levels Positive End-Expiratory Pressure on the Incidence of Atelectasis After Heart Surgery
Purpose
Prevention
Inclusion/Exclusion criteria
The inclusion criteria including: Patients candidate for non emergency open heart surgery (coronary artery bypass and heart valve surgery by sternotomy and cardiopulmonary bypass); Aged from 18 until 65 years; No ejection fraction less than 30% in the angiography form, preoperative; No history of chronic airway obstruction disease and lung trauma; No history of open heart surgery or lung surgery; No history of rib fractures and chest tube insertion; No history of trauma in the head or nose, neurologic disease and frequent sinus infections; No history of chemotherapy and using immunosuppressants three months prior to the surgery; No serum creatinine greater than 3.5 mg/Dl; No body mass index greater than 40 kg/m2; Consciousness level at 15 before surgery; Exclusion criteria including: Arterial systolic pressure less than 90 mmHg despite of fluid intake; Arterial blood pH less than 7.30; Arterial carbon dioxide pressure greater than 50 mmHg; Arterial oxygen saturation less than 80% despite of supplemental oxygen intake; Hemoglobin concentration less than 7 gr/dL; Aortic cross clamp time longer than 150 minutes; Cardiopulmonary bypass time longer than 240 minutes; Using intra aortic balloon pump (IABP) intraoperative and postoperative; Intubation over 24 hours; Also, the patient will be excluded from the study when he/she retransfers to the operating room or when he/she needs ventilator therapy protocols apart from of research protocols.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients are randomly assigned to the groups using random numbers table. The study is considered as Double blind, as except the researcher, all patients and radiologists are not aware of the randomized allocation of samples.

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
4816715793
Approval date
2015-07-23, 1394/05/01
Ethics committee reference number
IR.MAZUMS.REC.94-1855

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
Atelectasis
Timepoint
Two hours after extubation, the third day after surgery (72 hours of operation)
Method of measurement
Chest x-rays

Secondary outcomes

1

Description
Respiratory variable of arterial blood gas (arterial oxygen tension, arterial carbon dioxide tension, arterial oxygen saturation, arterial bicarbonate and arterial blood PH)
Timepoint
Before the intervention, one and four hours after the starting of the intervention, before extubation
Method of measurement
ABG test

2

Description
Arterial systolic pressure, diastolic blood pressure and mean arterial pressure
Timepoint
Before the intervention, one and four hours after the starting of the intervention, before extubation
Method of measurement
Advanced vital signs monitoring devices

3

Description
Heart rate
Timepoint
Before the intervention, one and four hours after the starting of the intervention, before extubation
Method of measurement
Advanced vital signs monitoring devices

4

Description
Respiratory rate
Timepoint
Before the intervention, one and four hours after the starting of the intervention, before extubation
Method of measurement
Counting the number of breaths per minute

5

Description
Tempreture
Timepoint
Before the intervention, one and four hours after the starting of the intervention, before extubation
Method of measurement
Advanced vital signs monitoring devices thermometer

Intervention groups

1

Description
Patient in the intermediate level of intervention will receive an average 8 cmH2O positive end-expiratory pressure (PEEP) for 4 hours, 30 minutes after entering the intensive care unit, (provided that the hemodynamic status is not disrupted). They will receive 5 cmH2O PEEP until the endotracheal tube removal.
Category
Prevention

2

Description
Patient in the high level of intervention will receive an average 10 cmH2O positive end-expiratory pressure (PEEP) for 4 hours, 30 minutes after entering the intensive care unit, (provided that the hemodynamic status is not disrupted). They will receive 5 cmH2O PEEP until the endotracheal tube removal.
Category
Prevention

3

Description
Patients in the control group receive 5 cmH2O positive end-expiratory pressure after surgery, 30 minutes after entering the intensive care unit until the removal of the endotracheal tube.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fateme Zahra hospitale
Full name of responsible person
Dr Masoumeh Bagheri- Nesami
Street address
Mazandaran University of Medical Sciences, three-way Joibar, highway Basij, Imam square, Sari, Mazandaran, Iran
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
Dr 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
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Dr Masumeh Bagheri Nesami
Position
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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