Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Airway Pressure Release Ventilation on patient' hemodynamic after Coronary Artery Bypass Graft

Protocol summary

Summary

The overall objective: to determine the effect of airway pressure release ventilation mode on hemodynamic parameters in patients after coronary artery bypass graft. This study is a clinical trial with a crossover design. Subjects and randomly allocated based on the number of samples needed to be divided into two groups turns harmoniously. Inclusion criteria: hemodynamic stability and EF> 40 and coronary artery bypass surgery without CPB is located on the pump. Exclusion criteria: shock, CPR and bleeding more than usual. The study sample size is 32 patients in two groups of 16 students. Intervention study, the position of the mode APRV mode for up to half an hour, compared with SIMV / PSV desired parameters to be measured. Expected outcome: patient's hemodynamic status is unchanged.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092414756N1**
Registration date: **2015-01-17, 1393/10/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-17, 1393/10/27

Registrant information

Name

Samaneh Zakeri

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-11-07, 1393/08/16

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Airway Pressure Release Ventilation on patient' hemodynamic after Coronary Artery Bypass Graft

Public title

Effect of mechanical ventilation on hemodynamic

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 40-70 years old; hemodynamic stability in the first visit; EF ≥ 40% ; RASS = -2 to -3; surgery OFF PUMP; CABG without repair or replace the valve; failure to perform CPR during surgery or before the study; failure to perform emergency surgery (out of routine preoperative); absence of underlying lung disease; lack of oxygenation and ventilation disorder; having hypertension before surgery. Exclusion criteria: CPR performed during study; the need to replace volume; -2< RASS <-3; bleeding more than 100ml / hr of Drains; need to have surgery again; pH arterial <7.25; dysrhythmia that lead to the development of hemodynamic changes.

Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Daneshgah Street. Qureshi building
City
Mashhad
Postal code
Approval date
2014-10-04, 1393/07/12
Ethics committee reference number
930444

Health conditions studied

1

Description of health condition studied
Coronary artery disease
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
cardiac index
Timepoint
before intervention, half an hour after intervention & half an hour after return to base mode
Method of measurement
lit/min/BSA

2

Description
stroke volume index
Timepoint
before intervention, half an hour after intervention & half an hour after return to base mode
Method of measurement
mi/BSA

3

Description
mean arterial pressure
Timepoint
before intervention, half an hour after intervention & half an hour after return to base mode
Method of measurement
mmHg

4

Description
systemic vascular resistance
Timepoint
before intervention, half an hour after intervention & half an hour after return to base mode
Method of measurement
Dynes/sec/cm5

Secondary outcomes

1

Description
arterial oxygen saturation
Timepoint
before intervention, half an hour after intervention & half an hour after return to basic mode
Method of measurement
percent

2

Description
ratio ofl arterial oxygen to inspired oxygen fraction
Timepoint
before intervention, half an hour after intervention & half an hour after return to basic mode
Method of measurement
number

3

Description
pressure of arterial co2
Timepoint
before intervention, half an hour after intervention & half

an hour after return to basic mode

Method of measurement

mmHg

4

Description

pressure of arterial oxygen

Timepoint

before intervention, half an hour after intervention & half an hour after return to basic mode

Method of measurement

mmHg

Intervention groups

1

Description

Intervention of this research is a ventilation mode is called Airway Pressure Release Ventilation that applied through ventilator and tracheal tube for half an hour. this mode is a inverse ratio mode that patient airway pressure between high pressure and low pressure is fluctuated.in this intervention, the duration of high pressure is 4.5 sec and duration of low pressure is 0.5 sec.The high-level pressure based on the patient's tidal volume required is determined.

Category

Other

2

Description

This study is a cross-over study and no control group. Intervention (APRV mode) compared with SIMV mode. synchronized intermittent mandatory ventilation is a usual mode of mechanical ventilation in research environment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital- Open heart ICU

Full name of responsible person

Street address

West Ebn-e-Sina Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciencse- research assisstance

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Daneshgah Street. Before Golestan intersection

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciencse- research assisstance

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

Javad Malekzadeh

Position

Bachelor' degree of nursing education- faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Shahram Amini

Position

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Person responsible for updating data

Contact
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Full name of responsible person
Samaneh Zakeri
Position
Student
Other areas of specialty/work
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Fax
Email
Web page address

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