

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)

Phone

+98 51 1270 0636

Email address

zakeris2@mums.ac.ir

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 \geq 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; $-2 < \text{RASS} < -3$; 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

ml/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 of 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 Science- research

assistance

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 Science- research assistance

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

Mashhad University of Medical Sciences

Full name of responsible person

Shahram Amini

Position

Associate Professor and Fellowship of Intensive Care Medicine

Other areas of specialty/work

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Postal code**Phone****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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Samaneh Zakeri

Position

Student

Other areas of specialty/work**Street address**