Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

An assessment effect of low tidal volume ventilation in on-pump Coronary artery bypass graft surgery on post-operative pulmonary complications.

Protocol summary

Study aim

Determining the effect of mechanical ventilation with low volume and number during cardiopulmonary pump in heart surgery with the occurrence of pulmonary, renal and liver complications after surgery.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, 60 participants

Settings and conduct

This study was conducted in Baqiyatullah Hospital with the aim of determining the effect of mechanical ventilation with low volume and number during cardiopulmonary pump in heart surgery with the occurrence of pulmonary, renal and liver complications after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Not a candidate for emergency surgeries 2. No history of open heart surgery 3. Not suffering from known liver, kidney and lung disease. Exclusion criteria: 1. Bleeding after surgery 2. The need for re-surgery for any reason

Intervention groups

After obtaining informed consent from ASA class 1 and 2 CABG candidates, 60 patients were randomly divided into two intervention and control groups of 30. After establishing standard monitoring and IBP and CVP, induction of anesthesia will be done with the same method in patients of both groups. After placing the patient under CPB, patients in the intervention group receive ventilation with a tidal volume (3-4 ml/kg) and a number of 6-8 breaths/minute. Control group doesn't receive any ventilation according to the hospital routine after undergoing CPB. Renal and hepatic parameters are recorded before surgery and on the first, second and third days after surgery. vital signs, duration of mechanical ventilation in ICU-OH, duration of hospitalization in ICU are recorded.

Main outcome variables

Evaluation of pulmonary, renal and hepatic complications after surgery, Evaluation of length of stay in the ICU, Evaluation of hospital costs, Evaluation of patients' satisfaction and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220102053598N1**
Registration date: **2023-02-15, 1401/11/26**
Registration timing: **prospective**

Last update: **2023-02-15, 1401/11/26**
Update count: **0**

Registration date

2023-02-15, 1401/11/26

Registrant information

Name

Seyed Alireza Amouzegar Zavareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8806 5203

Email address

s_a_amouzegar69@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An assessment effect of low tidal volume ventilation in on-pump Coronary artery bypass graft surgery on post-operative pulmonary complications.

Public title

An assessment effect of low tidal volume ventilation in on-pump Coronary artery bypass graft surgery on post-operative pulmonary complications.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not a candidate for emergency surgeries No history of known hepatic, renal and pulmonary disease No history of open heart surgery

Exclusion criteria:

Emergency cardiac surgery Positive history of hepatic, renal and pulmonary disease redo cardiac surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent from ASA class 1 and 2 CABG candidates, 60 patients were randomly divided into two intervention and control groups of 30. Participants were not aware of their group.

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining informed consent from ASA class 1 and 2 CABG candidates, 60 patients were randomly divided into two intervention and control groups of 30. After establishing standard monitoring and IBP and CVP, induction of anesthesia will be done with the same method in patients of both groups. After placing the patient under CPB, patients in the intervention group receive ventilation with a tidal volume (3-4 ml/kg) and a number of 6 to 8 breaths per minute. Patients in the control group do not receive any ventilation according to the hospital routine after undergoing CPB. Kidney (BUN, Cr) and liver (SGOT, SGPT, ALKP) parameters are recorded before surgery and on the first, second and third days after surgery. In addition to laboratory parameters, vital signs, duration of mechanical ventilation in ICU-OH, duration of hospitalization in ICU are recorded by a person who does not know the exposure status of patients. The outcome registrar was not aware of the patient group. After collecting and recording data, they are analyzed using SPSS statistical software.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Baqiyatallah Hospital

Street address

no 31, Orfi shirazi Ave, North Sheikh Bahae st, Mollasadra st, Tehran

City

Tehran

Province

Tehran

Postal code

1993653991

Approval date

2022-06-18, 1401/03/28

Ethics committee reference number

Ir.BMSU.BAQ.REC.1401.046

Health conditions studied

1

Description of health condition studied

Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

ICD-10 code

I25. 810

ICD-10 code description

آترواسکلروز پیوند(های) بای پس عروق کرونر بدون آنژین صدری

Primary outcomes

1

Description

Hepatic Enzymes

Timepoint

Before surgery, the fist, second and third days after surgery

Method of measurement

Serology laboratory

2

Description

Renal function parameters

Timepoint

Before surgery, the fist, second and third days after surgery

Method of measurement

Serology laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the patient is placed under CPB, they receive ventilation with a flow volume (3-4 ml/kg) and a number of 6 to 8 breaths per minute.Control group: after placing the patient under CPB, no ventilation will be done according to the usual method, and the patient's lungs will collapse during the pump and will not be ventilated.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiatallah Hospital

Full name of responsible person

Seyed Mohammad Reza Amouzegar Zavareh

Street address

Baqiatallah Hospital, st. Molasadra

City

Tehran

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1435915371

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+98 21 81261

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amouzegar12@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohsen Saberi

Street address

Baqiatallah Hospital, Mollasadra St.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Baqiatallah Hospital

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyed Mohammad Reza Amouzegar Zavareh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyed Mohammad Reza Amouzegar Zavareh

Position

Assistant Professor

Latest degree
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Person responsible for updating data

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Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available