Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment the Effect of Positive End-Expiratory Pressure (PEEP) of 15 CmH2O on the Amount of Bleeding After Emergency Coronary Artery Bypass Surgery (CABG) without Using Cardiopulmonary Bypass Pump.

Protocol summary

Study aim

Determination the Effect of Positive End-Expiratory Pressure (PEEP) of 15 CmH2O on the Amount of Bleeding After Emergency Coronary Artery Bypass Surgery (CABG) without Using Cardiopulmonary Bypass Pump.

Design

Blocking (blocks of four) Due to the lack of similar study and the pilot of this research, as well as the number of patients in other studies, the sample size was considered to be 50 patients in each group. This study has been proposed as a hypothesis by the researchers, and due to the lack of similar studies, it is only predicted that there is a difference in the reduction of bleeding after the operation. Considering the conditions of these patients and the importance of the issue, any reduction in bleeding is important.

Settings and conduct

All patients referred to the cardiac emergency of Imam Reza & Qaim hospitals with coronary artery occlusion who candidates for emergency coronary artery bypass surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients who have been diagnosed with coronary artery occlusion and referred to the cardiac emergency department of Imam Reza and Qaim Hospital and after performing the initial diagnostic procedures, are candidates for emergency Coronary artery bypass surgery Exclusion criteria: Patient's death, lack of consent to participate in the study

Intervention groups

In the intervention group, after bypass operation and usual treatment, including FFP injection, tranexamic acid, platelet injection and if necessary, return to the operating room, etc., patients in the ICU were treated with PEEP equivalent to 15 cm H2O until ventilators is needed. In the conventional treatment group, patients will be treated with PEEP equivalent to 5 cmH2O and other conventional treatments.

Main outcome variables

The amount of bleeding from pericardial and thoracic drains (in cc) in the first 6, 12, and 24 hours after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231021059798N1**
Registration date: **2023-11-19, 1402/08/28**
Registration timing: **retrospective**

Last update: **2023-11-19, 1402/08/28**
Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Ahmadreza Sadeghipour kermani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3844 8417

Email address

ahmadreza.sadeghipour22@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

2022-09-23, 1401/07/01

Actual recruitment end date

2023-05-21, 1402/02/31

Trial completion date

2023-05-21, 1402/02/31

Scientific title

Assessment the Effect of Positive End-Expiratory Pressure (PEEP) of 15 CmH2O on the Amount of Bleeding After Emergency Coronary Artery Bypass Surgery (CABG) without Using Cardiopulmonary Bypass Pump.

Public title

Assessment the Effect of Positive End-Expiratory Pressure (PEEP) of 15 CmH2O on the Amount of Bleeding After Emergency Coronary Artery Bypass Surgery (CABG) without Using Cardiopulmonary Bypass Pump

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who referred to the cardiac emergency department of Imam Reza Hospital with coronary artery occlusion and after performing the initial diagnostic procedures, are candidates for emergency Coronary artery bypass surgery (CABG). All patients who referred to the cardiac emergency department of Qaim Hospital with coronary artery occlusion and after performing the initial diagnostic procedures, are candidates for emergency Coronary artery bypass surgery (CABG).

Exclusion criteria:

Patient's death lack of consent to participate in the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking (blocks of four)- In order to ensure an equal number of patients in the intervention and control groups, 2 patients are assigned to the intervention and 2 patients to the control in each block. Allocation of patients to intervention group and control group in each block is completely random. For example, the sequence of AABB- ABBA- BABA and... can be created in each block according to randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to obtaining informed consent from the patients before entering the study, the patients do not know how to be assigned to the intervention or control group. Also, the data analyst does not know the group assigned to the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

No. 19, Farvardin 19, Naser Khosro Ave., Ahmad Abad Bivd., Mashhad City

City

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Province

Razavi Khorasan

Postal code

9176856587

Approval date

2022-04-26, 1401/02/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.708

Health conditions studied

1

Description of health condition studied

Coronary artery occlusion

ICD-10 code

I21.9

ICD-10 code description

Acute myocardial infarction, unspecified

Primary outcomes

1

Description

The amount of bleeding after CABG

Timepoint

In the first 6, 12, and 24 hours after surgery

Method of measurement

The amount of bleeding from pericardial and thoracic drains (in cc)

2

Description

Blood hemoglobin level

Timepoint

In the first 6, 12, 24 and 48 hours after surgery

Method of measurement

Cell Counter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after bypass operation and usual treatment, including FFP injection, tranexamic acid, platelet injection and if necessary, return to the operating room, etc., patients in the ICU were treated with PEEP equivalent to 15 cm H2O until ventilators is needed.

Category

Treatment - Other

2

Description

Control group: after bypass operation and usual treatment, including FFP injection, tranexamic acid, platelet injection and if necessary, return to the operating room, etc., patients in the ICU were treated with PEEP equivalent to 5 cm H2O until ventilators is needed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza and Qaim Hospitals

Full name of responsible person

Ahmad Reza Sadeghipour Kermani

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No. 19, Farvardin Ave., Naser khosro, Ahmad Abad Blvd., Qods Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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 Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Ahmad Reza Sadeghipour Kermani

Position

Resident Of Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Ahmad Reza Sadeghipour Kermani

Position
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Person responsible for updating data

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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
Not applicable

Data Dictionary
Not applicable