Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of retrograde autologous priming on anion gap of blood transfusion and glomerular filtration rate in coronary artery bypass grafting

Protocol summary

Study aim
The effect of retrograde autologous priming on anion gap of blood transfusion and glomerular filtration rate in coronary artery bypass grafting

Design
An interventional and random study will be conducted in two groups of 70 with a sample size of 140, double-blind and randomized in completely separate groups.

Settings and conduct
In this study, with a total sample size of 140 patients in a double-blind randomized clinical trial who undergo coronary heart surgery at Abu Ali Sinai Hospital in Shiraz, after the patients are under general anesthesia after skin preparation and sterilization, surgery with a median sternotomy approach, and heart and lung cannulation and After injecting 400 units/kg of heparin, they are connected to the cardiopulmonary pump, in the intervention group, 500 ml of the patient's blood is retrogradely replaced by 500 ml of the prime solution.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent, Patients 45 to 80 years old, Candidate patients for coronary artery surgery. Exclusion criteria: Acute infection, Steroid users, Vascular problems

Intervention groups
Intervention group 1 (case) After the patients are under general anesthesia, skin preparation, and surgical sterilization, with a median sternotomy approach and heart and lung cannulation. After injecting 400 U/KG of heparin, they are connected to the cardiopulmonary pump. In the tested group, 500 ml of the patient's blood is retrogradely replaced by 500 ml of the prime solution. Control group: After priming the oxygenator in the usual way using 1500 ml of Ringer's solution, pulseless blood flow with a flow of 2-2.4 liters per minute per square meter with an average decrease in temperature (32-34 centimeters) Grad) starts.

Main outcome variables
Arterial Blood Gas

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180922041084N8**
Registration date: **2022-10-11, 1401/07/19**
Registration timing: **prospective**

Last update: **2022-10-11, 1401/07/19**
Update count: **0**

Registration date
2022-10-11, 1401/07/19

Registrant information
Name
Maryam Tabibzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-21, 1401/08/30
Expected recruitment end date
2023-07-23, 1402/05/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of retrograde autologous priming on anion gap of blood transfusion and glomerular filtration rate in coronary artery bypass grafting

Public title

The effect of retrograde autologous priming on anion gap of blood transfusion and glomerular filtration rate in coronary artery bypass grafting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Patients 45 to 80 years old Candidate patients for coronary artery surgery

Exclusion criteria:

Patients with physical conditions higher than grade 3, based on the classification of the American Society of Anesthesiologists(ASA>3) Acute infection Steroid users Vascular problems Non-sinusoidal rhythm Complete branch block Myocardial infarction Recent third-degree block (in the last month) Severe pulmonary disease (based on the doctor's opinion and the use of pulmonary drugs) Kidney disorders (creatinine more than 1.5) Hematocrit less than 30% Discharge fraction less than 40%

Age

From **45 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the limited randomization method of the block randomization type. The size of all the blocks is the same. In this experiment, with a sample size of 140, we will have two groups of 70 blocks (including 35 blocks with a size of 4). The randomization list is also taken from the random sequence generation site www.sealedenvelope.com, which can generate a random sequence using the blocking method. The allocation ratio of the samples will be one to one and placed in two intervention groups 1 and the control group. Then, based on the obtained blocks and in the order of the allocation sequence, the necessary technology will be given to the patients. This study is double-blind

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, so that the patient and the personnel collecting information are unaware of the type of intervention in these patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

"Ethics Committee" of Shiraz University of Medical Sciences

Street address

7th floor, research assistant of Shiraz University of Medical Sciences, central building of Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2022-08-14, 1401/05/23

Ethics committee reference number

IR.SUMS.MED.REC.1401.234

Health conditions studied

1

Description of health condition studied

Coronary heart disease

ICD-10 code

I25.118

ICD-10 code description

Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris

Primary outcomes

1

Description

Atrial Fibrillation

Timepoint

The patient's ECG is evaluated before - during - after the opening of the aortic clamp and the start of heart contraction until the last day of the patient's hospitalization in the ICU.

Method of measurement

Through ECG monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Under general anesthesia, after skin preparation and surgical sterilization, with a median sternotomy approach and heart and lung cannulation, and after injecting 400 units/kg of heparin, they are connected to the cardiopulmonary pump. In group 1, we replace 500 ml of prime solution with 500 ml of the patient's blood in a retrograde manner.

Category
Treatment - Surgery

2

Description
Control group: For the patients in the control group, the standard method is used, in this method, after priming the oxygenator in the usual way, using 1500 ml of Ringer's solution, pulseless blood flow with a flow of 2-2.4 liters per minute per meter square) starts with a moderate decrease in temperature (32-34 centigrade). First, we start the pump slowly and then we remove the clamp on the Venus cannula so that the venous blood enters the oxygenator and then we increase the flow rate to normal.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Abu Ali Sina Hospital

Full name of responsible person
Seyedeh Toktam Seyedhoseyni

Street address
The new city of Sadra is the beginning of phase two

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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7th floor, research assistant of Shiraz University of Medical Sciences, central building of Shiraz University of Medical Sciences, Zand St

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Seyedeh Toktam Seyedhoseyni

Position
licensee

Latest degree
Bachelor

Other areas of specialty/work
Others

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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Assistant Professor of Anesthesiology, Cardiac Anesthesiology Fellowship

Latest degree
Subspecialist

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Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It is against the policies of our center.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available