

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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)

Phone

+98 71 3628 1460

Email address

dpt2370349433@sums.ac.ir

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

Shiraz

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Fars

Postal code

71994_67985

Phone

+98 71 3640 7063

Email

Otc.hospital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Mahtab Memarpour

Street address

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

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memarpour@sums.ac.ir

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

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

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7193711351

Phone

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Reza Joybarr

Position

Assistant Professor of Anesthesiology, Cardiac
Anesthesiology Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

MaryamTabibzadeh

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

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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