Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

comparison of the effect of modified and conventional hemofiltration and combination of the two methods during cardiopulmonary bypass during coronary artery bypass graft surgery (CABG) on kidney function

Protocol summary

Study aim
Comparison of the effect of hemofiltration with modified and conventional methods during heart and lung pumping on kidney function (24-hour urine volume, glomerular filtration rate and CrCl after surgery

Design
A clinical trial with three intervention groups with factorial groups. Two blinded strains. Randomized on 60 patients were assigned to three intervention groups using the block randomization method.

Settings and conduct
investigating the effect of two new (modified) and conventional (conventional) hemofiltration methods and the combination of those two methods on kidney function in patients who are candidates for coronary artery bypass surgery (CABG) and cardiopulmonary bypass. It will be performed on 60 patients in the operating room of the Chamran educational center in Isfahan. , human subjects are selected from CABG and cardiopulmonary bypass candidate patients admitted to Chamran Hospital in this study by calculating and comparing the indices of glomerular filtration rate (GFR), creatinine clearance rate and 24-hour urine test in time intervals before surgery; The morning after the surgery and the morning three days (72 hours) after the surgery, then compare the average of these indicators in the three mentioned groups to check the amount of kidney damage.

Participants/Inclusion and exclusion criteria
All patients between 35 and 60 years of age with indications for coronary artery bypass graft surgery who require a heart and lung pump should be admitted to Shahid Chamran Hospital in Isfahan.

Intervention groups
The three methods of intervention in this research include two common and new methods of hemofiltration and the combination of those two methods.

Main outcome variables
serum creatinine level; glomerular filtration rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231011059689N1**
Registration date: **2023-10-16, 1402/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-16, 1402/07/24**
Update count: **0**

Registration date
2023-10-16, 1402/07/24

Registrant information
Name
Ghazal Homayoon
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-13, 1402/07/21
Expected recruitment end date
2023-12-12, 1402/09/21
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of modified and conventional hemofiltration and combination of the two methods during cardiopulmonary bypass during coronary artery bypass graft surgery (CABG) on kidney function

Public title

comparison of the effect of the three methods of hemofiltration during CABG on kidney function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients between 35 and 60 years old consciously able to sign a consent letter for participating in this research a candidate for coronary artery bypass graft. recognized by a left ventricle ejection fraction of more than 45% recognized by a gloumeral filtarion rate between 70 and 120

Exclusion criteria:

patients recognized by a left ventricle ejection fraction of less than 45% recent MI a gloumeral filtration rate of less than 70 mili litrs per minute kidney failure serum creatinine of more than 1.3 miligrams per decilitr emergency surgery a history of diabetic nephropathy a conjoint valve surgery proteinuria

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients are assigned to three intervention groups using block randomization method. In this way, according to the three groups of intervention and the type of intervention, 120 blocks of 6 that are a combination of interventions will be formed. And then among these blocks, 810 blocks will be randomly selected and based on that, the patients in each block will be assigned to the desired intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted in a double-blind manner, so that the patient and the person analyzing the data will not know about the intervention groups.there will be no possibility of blinding for the doctor and nurse

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of isfahan university of medical science

Street address

No 412, fifth alley, Mehryar st, Janbazan st

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Province

Isfehan

Postal code

8179689367

Approval date

2023-10-11, 1402/07/19

Ethics committee reference number

IR.MUI.MED.REC.1402.235

Health conditions studied

1

Description of health condition studied

: Comparing the effect of hemofiltration with modified and conventional methods during heart and lung pumping on kidney function (24-hour urine volume, glomerular filtration rate and CrCl after surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

serum creatinine

Timepoint

before coronary artery bupass graft surgery - 24 hours after CABG - 72 hours after CABG

Method of measurement

Collection of venous blood sample and measurement of serum creatinine in clinical laboratory

2

Description

creatinine clearance

Timepoint

before coronary artery bupass graft surgery - 24 hours after CABG - 72 hours after CABG

Method of measurement

calculating the amount using the quantity of serum creatinine and the formula : CrCl(ml/min) = ((140-age)*lean body weight(kg))/(serum creatinine(mg/dl)*72) * (0.85 if female)

3

Description
gloumeral filtration rate
Timepoint
before coronary artery bupass graft surgery - 24 hours after CABG - 72 hours after CABG
Method of measurement
Calculation of the amount based on the amount of serum creatinine and a defined constant with the help of the Cockcroft-Gallt formula : eGFR=((140-age)*weight*constant)/(serum creatinine) constant = 1.23 for men and 1.04 for women

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the group in which hemofiltration is performed by the common method (CUF/Conventional). In this group, during heart and lung bypass, the blood is transferred to the hemofilter through the high-pressure part of cardioplegia and passes through the fibers and removes excess fluids and inflammatory factors.
Category
Treatment - Other

2

Description
Intervention group: Intervention group: the group in which hemofiltration is performed by a new or advanced method (MUF/modified). In this method, after completing the cardiopulmonary bypass, the blood is transferred to the cardioplegia head pump through the venous line and transferred to the hemofilter through the power of this pump, and after removing excess fluids and inflammatory factors, it is returned to the patient's arterial system through the arterial line.
Category
Treatment - Other

3

Description
Intervention group: A group in which both MUF (new) and CUF (common) methods are performed
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran cardiovascular surgery center
Full name of responsible person
Dr. Mehran Shahzamani
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the third moshtaq st. , salman farsi st. , chamran hospital, isfahan , iran
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Sponsors / Funding sources

1

Sponsor
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Web page address
https://mui.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Dr Mehran Shahzamani

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

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

Title and more details about the data/document
The informed consent form is given in the proposal and thesis. The clinical study report will be fully and in detail described in the text of the thesis and in the work implementation method section. The method of data analysis and statistical methods and analysis codes will be fully explained in the text of the thesis with the help of a respected statistician.

When the data will become available and for how long
The access period starts six months after the results are published

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
if a researcher employed in academic centers is interested in more information about data analysis further than what is written in the thesis / article they can contact the e-mail adress : g.homayoon@gmail.com

From where data/document is obtainable
Ghazal Homayoon . e-mail adress : g.homayoon@gmail.com

What processes are involved for a request to access data/document

Respected applicants can send an e-mail containing the text of the request for information with the detailed mention of the required information to the mentioned e-mail address, within 24 hours in response to the request for the desired information (or if it is not possible to share the information, the reason for it) with Send an email to them.

Comments