Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Zero-balance ultrafiltration method to evaluate the effect on clinical outcomes in patients undergoing coronary artery bypass surgery

Protocol summary

Summary

The purpose of this study was to determine the effect of ultrafiltration method Zero-balance the clinical outcome of patients undergoing coronary artery bypass graft (2) Design: This study was a randomized clinical trial with a control group in which the influence of ultrafiltration Z-Buf the clinical outcomes of patients undergoing cardiopulmonary bypass in the intervention and control groups will be investigated. (3)In the intervention group since the beginning of operation hemofilter connected to a cardiopulmonary bypass system and with constant internal tank volume intravenous normal saline or ringer by adding based on the patient's clinical condition, his blood will be filtered. High potassium in the form of normal saline solution, and if it is normal or low serum lactate ringer will be used. The priming volume of 1/5 liters considered in this study will be told that the remaining volume in the tank after filling pipes at a rate of 300 cc will be. In the event of a drop in hematocrit of 21% of packed red blood cells to increase this amount to over 21% will be used. In the control group routine will be carried out and any other method for ultrafiltration will not be used. (4)Participants, including conditions of entry and main output to study liver failure as ((AST> 40 unit / L) and (ALT> 40 unit / L) A history of heart surgery High serum creatinine 1/5 mg / dL, and patients who received the drug because before, during 5 days, have acute kidney failure. In both carotid narrowing of the carotid artery or one of its (5)Interventions: the effect of ultrafiltration using Z-Buf the clinical outcome of patients undergoing cardiopulmonary bypass in the intervention and control groups will be investigated (6) The main outcome variables were studied: clinical implications

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092229914N1**

Registration date: **2017-05-01, 1396/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

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Name of organization / entity

Iran university Of medical sciences

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research Iran university of medical sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Zero-balance ultrafiltration method to evaluate the effect on clinical outcomes in patients undergoing coronary artery bypass surgery

Public title
Ultrafiltration effect on coronary artery bypass surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Non-inclusion criteria Liver failure as ((AST> 40 unit / L) and (ALT> 40 unit / L);A history of heart surgery;High serum creatinine1/5mg / dL; And patients who received the drug because before during 5 days acute renal failure have had severe narrowing of the carotid both carotid or one of them; Surgery emergency; IE; Ejection fraction of the left ventricle less than 30 percent of patients with Severe failure right ventricle Hemoglobin less than 10;Mass index BMI greater than 40;Benign and malignant cancers;Clamped aortic bypass for more than 120 minutes and 150 minutes; Pulmonary function test abnormal preoperative FEV1 <65 Exclusion criteria Prime 8/5000 Autologus do the opposite; Using the CUF; Using MUF; Patient died during surgery; Use of Intraoperative balloon pump;Use of ECMO; The need to stay open sternum after surgery; The patient needs cardiopulmonary resuscitation
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the University of Medical Sciences
Street address
Hemmat Tehran
City
Tehran
Postal code
Approval date
2017-01-07, 1395/10/18
Ethics committee reference number
IR.IUMS.REC 1395.9311584001

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease
ICD-10 code
I25.0
ICD-10 code description
Atherosclerotic cardiovascular disease, so described

Primary outcomes

1

Description
Cerebral oxygenation
Timepoint
1.Preoperative2.Start operation3.Intraoperative4.Postoperative2
Method of measurement
Invos devices

2

Description
Arterial blood gases
Timepoint
Before surgery2.Start operation3.Intraoperative4.End the practice of5.6 hours after surgery
Method of measurement
Arterial blood gas measurement

3

Description
Liver enzymes
Timepoint
Preoperative and postoperative
Method of measurement
Measured by laboratory

4

Description
Kidney enzymes
Timepoint
Preoperative and postoperative
Method of measurement
Measured by laboratory

5

Description
Cardiac arrhythmia
Timepoint
Preoperative and postoperative
Method of measurement

ECG machine

Secondary outcomes

empty

Intervention groups

1

Description
Hemofilter action in the intervention group since the beginning of cardiopulmonary bypass connected to the system and maintain the volume of the tank by adding intravenous normal saline or ringer on the basis of clinical status, His blood will be filtered
Category
Treatment - Other

2

Description
In the control group there is
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajai Hospital
Full name of responsible person
Tahereh Najafi
Street address
Rajai Hospital, Valiasr Street, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice CHancellor For Research, Iran university Of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
Hemmat, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice CHancellor For Research, Iran university Of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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00
Fax
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty