Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effects of modified ultrafiltration on rotational thromboelastometry (ROTEM) and inflammatory cytokine response in patients under cardiopulmonary bypass surgery

Protocol summary

Summary

Patients undergoing elective coronary artery bypass using cardiopulmonary bypass complying with the inclusion criteria will be randomly assigned into two different groups: conventional filtration plus modified ultrafiltration and conventional filtration. Blood samples will be drawn from patients in three time points: after cross-clamp opening, after separation from pump and 24 hours after operation. Then cytokine levels will be measured using ELISA method.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017042127617N3**
Registration date: **2017-06-02, 1396/03/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

Hamidreza Pazoki-Toroudi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-05-08, 1396/02/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of modified ultrafiltration on rotational thromboelastometry (ROTEM) and inflammatory cytokine response in patients under cardiopulmonary bypass surgery

Public title

Investigating the effects of modified ultrafiltration on rotational thromboelastometry (ROTEM) and inflammatory cytokine response in patients under cardiopulmonary bypass surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients candidated for cardiopulmonary bypass surgery; cardiopulmonary bypass time from 50 to 120 minutes; number of grafts 3 or 4,/ Exclusion criteria: patient denying to participate in the study; cardiac conditions/comorbidities affecting the recovery after sternotomy; previous history of cardiac arrest; use of defibrilator during operation

Age

No age limit

Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
We will use simple randomization using random digits table to assign subjects to two parallel groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Hemmat expway, Next to Milad Tower
City
Tehran
Postal code
Approval date
2017-01-29, 1395/11/10
Ethics committee reference number
IR.IUMS.REC 1395.9311248001

Health conditions studied

1

Description of health condition studied
coronary artery disease
ICD-10 code
125.1
ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
ROTEM parameters
Timepoint
After declamp, after separation from pump, 24 hours after operation
Method of measurement
Plasma analysis using ROTEM machine

2

Description
Hemoglobin and hematocrit
Timepoint
Before and after operation
Method of measurement
Biochemical analysis

3

Description
Inflammatory cytokine response (IL-6, -8, -10 and TNF-alpha)
Timepoint
After declamp, after separation from pump, 24 hours after operation
Method of measurement
Plasma analysis using ELISA technique

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention model, conventional ultrafiltration will be performed during operation and modified ultrafiltration will be applied after cardiopulmonary bypass.
Category
Treatment - Other

2

Description
In the control group, only conventional ultrafiltration will be applied during operation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Farhad Gorjipour
Street address
Niyayesh Crossroad, Valiasr Avenue
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
Dr Seyed Ali Javad Mousavi
Street address
Next to Milad Tower, Hemmat Highway
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
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Farhad Gorjipour
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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

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