

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 21 8670 2708

Email address

pazoki49@gmail.com

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 candidate 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 defibrillator 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
I25.1

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

Position

Perfusionist practitioner

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Meysam Mortazian

Position

Cardiovascular surgery fellowship

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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