Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of ultrafiltration during cardiac surgery on Urinary neutrophil-associated lipocalin (NGAL)

Protocol summary

Summary

The aim of study is to evaluate the effect of hemofilter during cardiac surgery(with normal kidney function) on postoperative kidney, heart and lung finction. with consideration of inclusion and exclusion criteria 200 patients will be recruited for the study. They will be randomly assigned to either an ultrafiltration group (n=100) or to a control group (n=100). Ultrafiltration (Minntech hemoconcentrator, Hemocor HPH 1400) will be done during cardiopulmonary bypass (40cc/kg). Urinary NGAL were measured after urinary caheterizaion, and 2 hours after arrival at the intensive care unit, using ELISA test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103053438N3**
Registration date: **2011-06-03, 1390/03/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-03, 1390/03/13

Registrant information

Name

Mahnoosh Foroughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0635

Email address

m_foroughi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center Shaheed Beheshti Medical Sience

Expected recruitment start date

2010-10-07, 1389/07/15

Expected recruitment end date

2011-10-07, 1390/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ultrafiltration during cardiac surgery on Urinary neutrophil-associated lipocalin (NGAL)

Public title

Effect of ultrafiltration on kidney function

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Patients with coronary artery disease or vavular disease that come for elective first time on-pump operation will be recruited for the study. Exclusion criteria:cre>1.5mg/dl, less than 3 days interval between angiography(dye contrast) till operation, urinary infection(presence of bacteria on urinary exam),Chronic lung disease(history of bronchodilator use or FEV1 less than 60%on spirometry), combine operation(coronary and valve) and urgent/emergency cases

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Urology and Nephrology Research Center

Street address
Urology and Nephrology Research Center-aside Labbafi Hospital

City
Tehran

Postal code

Approval date
2010-09-30, 1389/07/08

Ethics committee reference number
27-3-89

Health conditions studied

1

Description of health condition studied
Chronic Ischemic Heart Disease

ICD-10 code
I25

ICD-10 code description
Chronic ischaemic heart disease

2

Description of health condition studied
Acute Renal Failure with tubular necrosis

ICD-10 code
N17.0

ICD-10 code description
Acute renal failure

Primary outcomes

1

Description
urinary NGAL

Timepoint
2 TIMES2 TIMES(after urinary caheterizaion, and 2 hours after arrival at the intensive care unit)

Method of measurement
ELISA

Secondary outcomes

1

Description
serum creatinin

Timepoint
daily for 4 days

Method of measurement
laboratory equipment

2

Description
intubation time

Timepoint
from entry to ICU till extubation

Method of measurement
hour

3

Description
blood product requirement

Timepoint
during operation

Method of measurement
unit

4

Description
chest tube drainage

Timepoint
from entry to ICU till chest tube removal

Method of measurement
ml

Intervention groups

1

Description
They will be randomly assigned to either an ultrafiltration group (n=100) or to a control group (n=100).
Ultrafiltration (Hemocor HPH 1400) will be done during cardiopulmonary bypass (40cc/kg).

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Cardiac Surgery Ward- M odarres Hospital
Full name of responsible person
Mahnoosh Foroughi
Street address
Saadat Abad.Modarres Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology and Nephrology Research Center
Full name of responsible person
Dr. Shabnam Golshan
Street address
Urology and Nephrology Research Center- aside Labbafi Hospital
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology and Nephrology Research Center
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
Modarres Hospital
Full name of responsible person
Mahnoosh Foroughi
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Cardiac Surgeon
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact
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Clinical Developement and ResearchCenter
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Email
m_foroughi@sbmu.ac.ir
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