

# 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 function. 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 catheterization, 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 Science

##### 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 valvular 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 TIMES 2 TIMES (after urinary catheterization, 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

m\_foroughi@sbm.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Clinical Research and Development Center  
**Full name of responsible person**  
Mahnoosh Foroughi  
**Position**  
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**Other areas of specialty/work**  
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## 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  
**City**  
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**  
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Modarres Hospital  
**Full name of responsible person**  
Mahnoosh Foroughi  
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## Person responsible for updating data

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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*