

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluating the effect of ubiquinone (CoQ10) on the prevention of postoperative Acute Kidney Injury (AKI) following Coronary Artery Bypass Grafting surgery (CABG)

#### Protocol summary

##### Study aim

Evaluation of ubiquinone effects on the prevention of Acute Kidney Injury after Coronary Artery Bypass Graft surgery

##### Design

In this study, 50 patients who are candidates for Coronary Artery Bypass Graft surgery and referred to Masih Daneshvari Hospital in Tehran are enrolled in the study. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

##### Settings and conduct

Place of study: Masih Daneshvari Hospital How to do the study: 50 patients who are candidates for Coronary Artery Bypass Graft surgery are randomly divided into two intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who undergo Coronary Artery Bypass Grafting at Masih Daneshvari Hospital are randomly enrolled in the study; there are no restrictions on age and gender for entry. Exclusion criteria: History of hypersensitivity reaction to ubiquinone; Chronic liver failure (Stage II & III); Chronic Kidney Disease (Stage IV & V) or patients with Glomerular Filtration Rate of lower than 30 ml/min; Patient with INR of more than 2.5; Patients who receive anti-inflammatory agents at least two weeks before admission; Patients who undergo emergency CABG.

##### Intervention groups

In the drug group, patients will receive 600 mg of ubiquinone (300 mg every 12 hours) for 2 days before surgery. The control group does not receive the drug.

##### Main outcome variables

Incidence of Acute Kidney Injury; Increasing of NGAL biomarker

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N16**

Registration date: **2020-05-28, 1399/03/08**

Registration timing: **retrospective**

Last update: **2020-05-28, 1399/03/08**

Update count: **0**

##### Registration date

2020-05-28, 1399/03/08

##### Registrant information

##### Name

Farzaneh Dastan

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 270 5933

##### Email address

f\_dastan@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Faculty of Pharmacy, Shahid Baheshti University of Medical Sciences

##### Expected recruitment start date

2016-06-19, 1395/03/30

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

2016-06-19, 1395/03/30

##### Actual recruitment end date

2017-06-20, 1396/03/30  
**Trial completion date**  
2017-07-21, 1396/04/30

**Scientific title**

Evaluating the effect of ubiquinone (CoQ10) on the prevention of postoperative Acute Kidney Injury (AKI) following Coronary Artery Bypass Grafting surgery (CABG)

**Public title**

Evaluating the effect of ubiquinone (CoQ10) on the prevention of Acute Renal Injury following open heart surgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The patients who are candidates for Coronary Artery Bypass Graft surgery in Masih Daneshvari Hospital

**Exclusion criteria:**

History of hypersensitivity reaction to ubiquinone Chronic liver failure (Stage II & III) Chronic kidney disease (Stage IV & V) or patients with Glomerular Filtration Rate of lower than 30 ml/min Patient with INR of more than 2.5 Patients who receive anti-inflammatory agents at least two weeks before admission Patients who undergo emergency CABG.

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**  
More than 1 sample in each individual  
Number of samples in each individual: **3**  
Plasma sample  
Actual sample size reached: **50**  
More than 1 sample in each individual  
Actual sample size in each individual: **3**  
Plasma sample

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization method using table of random numbers is applied to the study population. Unit of randomization is individual. Even and odd numbers are chosen for the case and the control group, respectively. Numbered drug containers are applied for allocation concealment.

**Blinding (investigator's opinion)**

Not 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 School of Pharmacy, Nursing, and Midwifery; Shahid Beheshti University of Medica

**Street address**

No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

141556153

**Approval date**

2016-03-01, 1394/12/11

**Ethics committee reference number**

IR.SBMU.PHNM.1394.311

## Health conditions studied

1

**Description of health condition studied**

Acute Kidney Injury

**ICD-10 code**

N99.0

**ICD-10 code description**

Postprocedural (acute) (chronic) kidney failure

## Primary outcomes

1

**Description**

Acute Kidney Injury

**Timepoint**

before surgery and 6 & 24 hours after surgery

**Method of measurement**

Evaluation of NGAL kits

## Secondary outcomes

1

**Description**

Checking of inflammatory biomarkers

**Timepoint**

before surgery and 24 hours after surgery

**Method of measurement**

Evaluation of CRP kit

## Intervention groups

## 1

### Description

Intervention group: administration of ubiquinone oral tablets, 300 mg, 2 times a day (every 12 hours), for 2 days (48 hours before surgery)

### Category

Prevention

## 2

### Description

Control Group: will not receive the drug .

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Masih Daneshvari Hospital

#### Full name of responsible person

Farzaneh Dastan

#### Street address

Masih Daneshvari Hospital, Daar-Abad, Shahid Bahonar St. (Niavaran)

#### City

Tehran

#### Province

Tehran

#### Postal code

1956944413

#### Phone

+98 21 2712 3000

#### Email

fzh.dastan@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zarghi

#### Street address

3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1983963113

#### Phone

+98 21 23871

#### Email

mpd@sbm.ac.ir

#### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Shahid Beheshti University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Masih Daneshvari Hospital

#### Full name of responsible person

Alireza Jahangirifard

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

#### Street address

Masih Daneshvari Hospital, Daar-Abad, Shahid Bahonar St. (Niavaran)

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Tehran

#### Province

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#### Fax

#### Email

alirezajahangiri@sbm.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Farzaneh Dastan

#### Position

Assistant Professor, Clinical Pharmacy Specialist

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Valieasr St., Intersection of Niyayesh Highway, Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy

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**Province**

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**Web page address**

**Email**

eskandari\_raha@yahoo.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

All potential data can be shared after blinding.

**When the data will become available and for how long**

Six months after results publishing

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

For research purposes and meta-analysis studies

**From where data/document is obtainable**

Dr. Farzaneh Dastan, Masih Daneshvari Hospital, Daar-Abad, Niavaran

**What processes are involved for a request to access data/document**

Official letter to the researchers

**Comments**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Masih Daneshvari Hospital

**Full name of responsible person**

Raha Eskandari

**Position**

Pharm.D

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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