# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Evaluating the prescription of short-term and medium-term effects of coenzyme Q۱۰ on the inflammatory system and renal function in patients undergoing open heart surgery

## Protocol summary

**Study aim**

Determining the effect of short- and medium-term administration of coenzyme Q10 on the inflammatory system (IL-6, IL-10) and kidney function in patients undergoing open heart surgery.

**Design**

The clinical trial with randomized control and intervention group, phase 3 will be conducted on 81 patients and the collected data will be analyzed with SPSS 22.

**Settings and conduct**

The sampling site is Shahid Beheshti Hospital in Qom. Patients are classified into two control and intervention groups based on the random numbers table. The intervention group will receive coenzyme 10 tablets, 300 mg, twice a day, for 2 days before the operation until discharge. Patients in the control group will receive placebo in the same way. In order to measure and evaluate inflammatory factors, 2 ml of blood samples are taken in three time intervals. Then it will be sent to the laboratory for serology tests by Eliza kit. In order to evaluate kidney function, Cr, BUN and GFR will be determined in the clinical laboratory.

**Participants/Inclusion and exclusion criteria**

Entry criteria: age over 18 years, suffering from CAD, glomerular filtration rate greater than 45 ml/min. Exclusion criteria: treatment with coenzyme Q-10, high-risk patients undergoing emergency coronary angiography, presence of sensitivity to Q-10, people with kidney failure who need dialysis; Exposure to contrast media in the past 7 days, left ventricular ejection fraction <30, administration of N-acetyl-cysteine within 48 hours after surgery, and refusal to consent

**Intervention groups**

Patients in the intervention group will receive CoQ10 tablets, 300 mg, twice a day every 12 hours, in the period of two days before the operation until the time of discharge from the ICU department. Patients in the control group will receive the placebo in the same way.

**Main outcome variables**

Factors interleukin-10, interleukin-6, Cr,BUN, GFR

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230218057444N1**
Registration date: **2023-03-06, 1401/12/15**
Registration timing: **prospective**

Last update: **2023-03-06, 1401/12/15**
Update count: **0**

**Registration date**

2023-03-06, 1401/12/15

**Registrant information**

**Name**

Mina Badi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-03-25, 1402/01/05

**Expected recruitment end date**

2024-03-24, 1403/01/05

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the prescription of short-term and medium-term effects of coenzyme Q۱۰ on the inflammatory system and renal function in patients undergoing open heart surgery

**Public title**

Evaluating the prescription of short-term and medium-term effects of coenzyme Q۱۰ on the inflammatory system and renal function in patients undergoing open heart surgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The inclusion criteria for all patients over 18 years of age, suffering from coronary artery disease undergoing CABG surgery, is the glomerular filtration rate (GFR) greater than 45ml/min.

**Exclusion criteria:**

current coenzyme Q10 therapy, which has high-risk features that warrant urgent coronary angiography (within 4 hours); the existence of sensitivity to CoQ10, people with kidney failure who need dialysis; Exposure to contrast media in the past 7 days, left ventricular ejection fraction (LVEF) <30, administration of N-acetylcysteine within 48 hours postoperatively, and refusal of consent.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **41**

More than 1 sample in each individual

Number of samples in each individual: **3**

In order to measure and evaluate inflammatory factors, 2 ml of arterial blood samples are taken at three time intervals at the beginning of the operation, after cardio-pulmonary bypass and 24 hours after entering the ICU. Then, the sample is immediately sent to the relevant laboratories to measure interleukin-10 and interleukin-6 factors, and serology tests are measured by the ELISA kit of MabTag GmbH - Germany. In order to evaluate kidney function, 2 ml of venous blood samples are sent to the relevant laboratory in three time periods before the operation, after entering the ICU and 4 days later, to measure the level of creatinine, blood urea nitrogen and glomerular filtration rate (GFR) of the kidney. .

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For randomization, an online random number table is used. Odd numbers are included in the control group and even numbers are included in the experimental group

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, after explaining to the patient and obtaining informed consent to participate in the research study, and the use of the drug and its effects, the patient has no knowledge of the type of drug. People in the control group were also given a placebo so that they did not know the type of drug. In order to prevent errors, the outcome evaluator will be unaware of the type of drug injection and the allocation of people in groups

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

**Street address**

Qadir Blvd Pardis University

**City**

Qom

**Province**

Ghoum

**Postal code**

0000000000

**Approval date**

2023-01-27, 1401/11/07

**Ethics committee reference number**

IR.MUQ.REC.1401.219

## Health conditions studied

### 1

**Description of health condition studied**

Evaluating the prescription of short-term and medium-term effects of coenzyme Q10 on the inflammatory system and renal function in patients undergoing openheart surgery

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**

Measurement of interleukin-10 and interleukin-6 factorsIn order to evaluate the performance of all three parameters, creatinine level, blood urea nitrogen and glomerular filtration rate (GFR) are checked.

**Timepoint**

Patients in the intervention group will receive CoQ10 tablets, 300 mg, twice a day every 12 hours, in the period of two days before the operation until the time of discharge from the ICU department and sending to the POST ICU department. Patients in the control group will receive the placebo in the same way, that is, from two days before the operation until the time of discharge from the ICU. Anesthesia induction will be done for all patients with sufentanil 2 µg/kg, nesdonal 3 mg/kg and pancuronium 0.1 mg/kg, and anesthesia will be maintained with 0.5-1% isoflurane and during cardiopulmonary bypass with Pancranium 0.1 mg/kg/h, fentanyl 1-2 µg/kg, and midazolam 0.5-1-1 kg/mg are maintained, and all patients will receive heparin 300 u/kg before cardiopulmonary bypass; until the active coagulation time (ACT) is higher than 480 seconds. . Crystalloid (2000 cc Ringer) and colloid (50 cc albumin) are used to prime the oxygenator in both groups. During CPB, additional heparin will be prescribed to reach the target ACT. After completing CPB and disconnecting from the heparin pump, it is neutralized with protamine sulfate 1 mg per 100 units of heparin; to reach the ACT target of 80-120. In order to measure and evaluate inflammatory factors, 2 ml of arterial blood samples are taken in three time periods at the beginning of the operation, after cardio-pulmonary bypass and 24 hours after entering the ICU. Then, the sample is immediately sent to the relevant laboratories to measure interleukin-10 and interleukin-6 factors, and serology tests are measured by the ELISA kit of MabTag GmbH - Germany.In order to evaluate the performance of all three parameters, creatinine level, blood urea nitrogen and glomerular filtration rate (GFR) are checked. In this way, 2 ml of venous blood samples are sent to the relevant laboratory in three time periods before the operation, after entering the ICU and 4 days later, to measure the amount of creatinine, blood urea nitrogen of the kidney. The concentration of blood urea nitrogen and serum creatinine will be determined using an automatic biochemical analyzer (Hitachi 7600, Japan) in the clinical laboratory. The initial GFR of the patient is calculated before taking the Q10 drug, after entering the ICU and 4 days later.

**Method of measurement**

The following guidelines are used to determine which stage of CKD is most consistent with GFR results:Stage 1 kidney damage with normal kidney function GFR 90 or higherStage 2 mild loss of kidney function GFR 60-89Stage 3A mild to moderate decrease in kidney function GFR 45-59Stage 3B moderate to severe loss of kidney function GFR 30-44Stage 4 severe loss of kidney function GFR 29-15Step 5 - The final stepThe normal range of GFR is usually 90 or more, although it can vary by age. Stage I CKD also has a GFR range of 90 or higher because kidney damage is minimal at this stage. To diagnose CKD caused by surgery, additional tests are done to help diagnose CKD, including: a history of high blood pressure, presence of swelling in the legs, urinary tract infections, and abnormal urine tests (protein in the urine). Also, based on the classification of acute kidney injury, a sudden increase in serum creatinine to 0.3 mg/dL or more (426.4 µmol/L) in 48 hours or an increase in serum creatinine of 50% or more (1.5 times the initial value) or reduction of urine output (oliguria 0.5-1 ml/kg per hour, for 6 hours) will be considered as the first stage of kidney damage.All patients will be transferred to cardiac intensive care unit after surgery and will be mechanically ventilated with simultaneous mandatory intermittent ventilation (SIMV) and pressure support (PS).On the third day after surgery, patients are transferred to the postoperative care unit based on the following criteria: hemodynamic status with acceptable oxygenation and ventilation, conscious level, absence of life-threatening arrhythmias, active bleeding, electrolyte abnormalities, absence Delirium and severe anemia (Hgb <8 g/dL). Before transferring patients, urinary catheter and pericardial drainage tube will be removed.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Patients will be divided into two control and intervention groups based on random sampling (permutation blocks). Patients in the intervention group will receive CoQ10 tablets, 300 mg, twice a day every 12 hours, in the period of two days before the operation until the time of discharge from the ICU department and sending to the POST ICU department. Patients in the control group will receive the placebo in the same way, that is, from two days before the operation until the time of discharge from the ICU. Anesthesia induction will be done for all patients with sufentanil 2 µg/kg, nesdonal 3 mg/kg and pancuronium 0.1 mg/kg, and anesthesia will be maintained with 0.5-1% isoflurane and during cardiopulmonary bypass with Pancranium 0.1 mg/kg/h, fentanyl 1-2 µg/kg, and midazolam 0.5-1-1 kg/mg are maintained, and all patients will receive heparin 300 u/kg before cardiopulmonary bypass; until the active coagulation time (ACT) is higher than 480 seconds. . Crystalloid (2000 cc Ringer) and colloid (50 cc albumin) are used to prime the oxygenator in both groups. During CPB, additional heparin will be prescribed to reach the target ACT. After completing CPB and disconnecting from the heparin pump, it is neutralized with protamine sulfate 1 mg per 100 units of heparin; to reach the ACT target of 80-120. In order to measure and evaluate inflammatory factors, 2 ml of arterial blood samples are taken in three time periods at the beginning of the operation, after cardio-pulmonary bypass and 24 hours after entering the ICU. Then, the sample is immediately sent to the

relevant laboratories to measure interleukin-10 and interleukin-6 factors, and serology tests are measured by the ELISA kit of MabTag GmbH - Germany.In order to evaluate the performance of all three parameters, creatinine level, blood urea nitrogen and glomerular filtration rate (GFR) are checked. In this way, 2 ml of venous blood samples are sent to the relevant laboratory in three time periods before the operation, after entering the ICU and 4 days later, to measure the amount of creatinine, blood urea nitrogen of the kidney. The concentration of blood urea nitrogen and serum creatinine will be determined using an automatic biochemical analyzer (Hitachi 7600, Japan) in the clinical laboratory. The initial GFR of the patient is calculated before taking the Q10 drug, after entering the ICU and 4 days later.

**Category**

Prevention

**2**

**Description**

Control group: Patients will be divided into two control and intervention groups based on random sampling (permutation blocks). Patients in the intervention group will receive CoQ10 tablets, 300 mg, twice a day every 12 hours, in the period of two days before the operation until the time of discharge from the ICU department and sending to the POST ICU department. Patients in the control group will receive the placebo in the same way, that is, from two days before the operation until the time of discharge from the ICU. Anesthesia induction will be done for all patients with sufentanil 2 µg/kg, nesdonal 3 mg/kg and pancuronium 0.1 mg/kg, and anesthesia will be maintained with 0.5-1% isoflurane and during cardiopulmonary bypass with Pancranium 0.1 mg/kg/h, fentanyl 1-2 µg/kg, and midazolam 0.5-1-1 kg/mg are maintained, and all patients will receive heparin 300 u/kg before cardiopulmonary bypass; until the active coagulation time (ACT) is higher than 480 seconds. . Crystalloid (2000 cc Ringer) and colloid (50 cc albumin) are used to prime the oxygenator in both groups. During CPB, additional heparin will be prescribed to reach the target ACT. After completing CPB and disconnecting from the heparin pump, it is neutralized with protamine sulfate 1 mg per 100 units of heparin; to reach the ACT target of 80-120. In order to measure and evaluate inflammatory factors, 2 ml of arterial blood samples are taken in three time periods at the beginning of the operation, after cardio-pulmonary bypass and 24 hours after entering the ICU. Then, the sample is immediately sent to the relevant laboratories to measure interleukin-10 and interleukin-6 factors, and serology tests are measured by the ELISA kit of MabTag GmbH - Germany.In order to evaluate the performance of all three parameters, creatinine level, blood urea nitrogen and glomerular filtration rate (GFR) are checked. In this way, 2 ml of venous blood samples are sent to the relevant laboratory in three time periods before the operation, after entering the ICU and 4 days later, to measure the amount of creatinine, blood urea nitrogen of the kidney. The concentration of blood urea nitrogen and serum creatinine will be determined using an automatic biochemical analyzer (Hitachi 7600, Japan) in the clinical laboratory. The initial GFR of the patient is calculated before taking the Q10 drug, after entering the ICU and 4 days later.

**Category**

Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Shahid Beheshti Hospital
**Full name of responsible person**
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**Street address**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Ghoum University of Medical Sciences
**Full name of responsible person**
Motahareh Ghodrati
**Street address**
Shahid Beheshti blv, Shahid Beheshti Hospital
**City**
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**Province**
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**Postal code**
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**Email**
bmc@muq.ac.ir
**Web page address**
http://bmc.muq.ac.ir/

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ghoum 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**

Ghoum University of Medical Sciences

**Full name of responsible person**

Motahareh Ghodrati

**Position**

Perfusionist

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesia

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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Motahareh Ghodrati

**Position**

Perfusionist

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

The main outcomes of the study will be accessed for each patient

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

Access to the data will be free forever after the article is published

**To whom data/document is available**

Academic institutions and researchers in the relevant research field

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

The data will be used by mentioning the names of the researchers doing the project

**From where data/document is obtainable**

They can communicate with the responsible author of the article and project manager through email

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

After receiving the e-mail by the researchers, the information will be provided to the requester within a week

**Comments**