Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 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

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Mina Badi

Name of organization / entity

Country

Iran (Islamic Republic of)

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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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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Web page address
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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 updating data

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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