

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Effect of coenzyme Q10 Supplementation on Metabolic Syndrome Parameters, lipid peroxidation, hs-CRP and homocysteine in patients with metabolic syndrome.

#### Protocol summary

##### Summary

In this study, the people in intervention and control group are chosen by using the method of random sampling among patients with metabolic syndrome, they were chosen in the KER CARDS project which is a population study in the city of Kerman from 1388-1390. It is done so that 60 of the patients will be chosen according to the standards of entering the study and will be divided to two control and intervention groups by using random allocation software. In the beginning of the study Anthropometric measurements are done. 10cc blood sample after fasting 8 to 12 hours for measurement of HDL cholesterol, triglycerides, LDLCholesterol, total cholesterol, fasting blood sugar (FBS), homocysteine, MDA and hs-CRP levels is collected. After avoiding any body activity for 5 minutes, blood pressure of the person is measured and after another 5 minutes of rest, it is measured again and we use the mean of these two blood pressures. After the primary measurements 200 mg coenzyme Q10 is prescribed daily for intervention group and placebo for control group. After the intervention period for 3 months all the measurements mentioned above is done again to survey any changes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012101311092N2**

Registration date: **2012-11-12, 1391/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-11-12, 1391/08/22

#### Registrant information

##### Name

Najmeh Rafiei Moghadam

##### Name of organization / entity

Shahid Sadoghi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1624 0691

##### Email address

rafiee.najmeh@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences and Health Services

#### Expected recruitment start date

2012-10-20, 1391/07/29

#### Expected recruitment end date

2012-10-25, 1391/08/04

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of coenzyme Q10 Supplementation on Metabolic Syndrome Parameters, lipid peroxidation, hs-CRP and homocysteine in patients with metabolic syndrome.

#### Public title

Effect of Q10 in the treatment of metabolic syndrome

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: 1. Having the metabolic syndrome

according to the NCEP ATP III definition: According to the NCEP ATP III definition of having at least 3 of the following conditions: a) Abdominal obesity (waist circumference  $\geq 102$  cm in men and  $\geq 88$  cm in women) b) High blood pressure (systolic blood pressure  $\geq 130$  mm Hg and / or diastolic blood pressure  $\geq 85$  mm Hg) c) Low HDL-C ( $< 40$  mg/ dl in men and  $< 50$  mg/ dl in women) d) TG  $\geq 150$  mg/ dl e) FBS  $\geq 100$  mg/ dl 2. Being the age limit from 35 to 55 years 3. Patients with hypertension treated with anti-hypertensive drugs in the past 3 months have not changed and changes in drug therapy not occur during the study period. 4. Patients with diabetes who their treatment in the past 6 weeks has not changed (Changes in drug therapy not occur during the study period) 5. Consent to participate in the study. Exclusion criteria: 1. Statin use in the last month 2. History of cardiovascular disease in the past three months 3. Having an active infection 4. Risk of renal failure 5. Liver disease (viral hepatitis, treatments for liver disease) 6. Alcohol Consumption 7. Pregnancy or taking contraceptive drugs 8. History of hospitalization in the past 2 months 9. consumption of Nutritional supplements such as vitamins, trace elements, antioxidants

**Age**

From **35 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Yazd University of Medical Sciences Ethics Committee

**Street address**

Bahonar Square

**City**

Yazd

**Postal code**

8916978477

**Approval date**

2012-07-07, 1391/04/17

**Ethics committee reference number**

51242 / 1/ 17/پ

**Health conditions studied****1****Description of health condition studied**

Metabolic Syndrome

**ICD-10 code**

E78.8

**ICD-10 code description**

Other disorders of lipoprotein metabolism

**Primary outcomes****1****Description**

Fasting Plasma Glucose

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

Enzymatic methods

**2****Description**

HDL Cholesterol

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

colorimetry

**3****Description**

Blood pressure

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

sphygmomanometer

**4****Description**

waist circumference

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

tape

**5****Description**

TG

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

Enzymatic methods

**6****Description**

malondialdehyde

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

thiobarbituric acid method

**7****Description**

hs-CRP

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

ELISA

**8****Description**

Homocysteine

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

colorimetry

**Secondary outcomes****1****Description**

total cholesterol

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

colorimetry

**2****Description**

Anthropometric indicators: weight, height, body mass index, waist circumference, hip circumference and waist to hip ratio

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

Standard procedures using scale, tape and equations

**3****Description**

LDL cholesterol

**Timepoint**

at the beginning of the study and 3 month after intervention

**Method of measurement**

colorimetry

**Intervention groups****1****Description**

Intervention group:Q10,100 mg soft gel capsule twice a day for 3 month

**Category**

Treatment - Drugs

**2****Description**

Placebo group: placebo tablets containing 100 mg of soy oil twice a day for 3 months

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kerman Physiology Research Center

**Full name of responsible person**

Dr Gholamreza Usefzadeh

**Street address**

Shariati Av

**City**

Kerman

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University Of Medical Sciences

**Full name of responsible person**

Dr Hassan Mozaffari Khosravi

**Street address**

Bahonar sq

**City**

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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**

Yazd University Of Medical Sciences

**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*

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Kerman Physiology Research Center  
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Specialist in endocrinology and metabolism  
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## Person responsible for scientific inquiries

### Contact

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Shahid Sadoghi University of Medical Sciences  
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## Person responsible for updating data

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Shahid Sadoghi University Of Medical Sciences  
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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*