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
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Iran (Islamic Republic of)
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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 ≥102 cm in men and≥ 88 cm in women) b) High blood pressure (systolic blood pressure≥130 mm Hg and / or diastolic blood pressure≥85 mm Hg) c)Low HDL-C (< 40 mg/ dl in men and < 50 mg/ dl in women) d)TG ≥150 mg/ dl e)FBS ≥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 occure 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 Univesity 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 begining of the study and 3 month after intervention

Method of measurement
Enzymatic methods

2

Description
HDL Cholesterol

Timepoint
at the begining of the study and 3 month after intervention

Method of measurement
colorimetry

3

Description
Blood pressure

Timepoint
at the begining of the study and 3 month after intervention

Method of measurement
sphygmomanometer

4

Description
waist circumference

Timepoint
at the begining of the study and3 month after intervention

Method of measurement
tape

5

Description
TG

Timepoint
at the begining of the study and 3 month after intervention
Method of measurement
Enzymatic methods

6

Description
malondialdehyde
Timepoint
at the begining of the study and 3 month after intervention
Method of measurement
thiobarbituric acid method

7

Description
hs-CRP
Timepoint
at the begining of the study and 3 month after intervention
Method of measurement
ELISA

8

Description
Homocysteine
Timepoint
at the begining of the study and 3 month after intervention
Method of measurement
colorimetry

Secondary outcomes

1

Description
total cholesterol
Timepoint
at the begining 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 begining 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 begining 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
Yazd
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

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman Physiology Research Center

Full name of responsible person

Dr Gholamreza Usefzadeh

Position

Specialist in endocrinology and metabolism

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoghi University of Medical Sciences

Full name of responsible person

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Position

PHD,nutrition

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Person responsible for updating data

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Name of organization / entity

Shahid Sadoghi University Of Medical Sciences

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Najmeh Rafiei Moghadam

Position

MS student of Health Sciences in Nutrition

Other areas of specialty/work

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City

Yazd

Postal code

Phone

00

Fax

Email

Web page address

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