Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of coenzyme Q10 supplementation on glycemic control, inflammatory markers, lipid profile, oxidative stress and blood pressure in type 2 diabetic patients: a placebo-controlled trial

Protocol summary

Summary

The aim of this study is to determine the effect of coenzyme Q10 supplementation on glycemic control, inflammatory markers, lipid profile, oxidative stress and blood pressure in type 2 diabetic patients. In this single blind study, a total number of 54 patients will be selected from Shiraz health care centers. They will be divided into two groups of intervention (200 mg coenzyme Q10) and control (placebo consumers) by simple random sampling and will be intervened for eight weeks. Blood samples will be collected from the fasted (12 hours) subjects at the beginning and at the end of the study. Fasting blood sugar, hemoglobin A1c, insulin, total cholesterol, HDL-cholesterol, LDL-cholesterol, triglyceride, highly sensitive C reactive protein and malondialdehyde levels as well as insulin resistance and blood pressure are the factors which will be assessed in the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121711785N1**
Registration date: **2013-02-01, 1391/11/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-02-01, 1391/11/13

Registrant information

Name

Mahsa Moazen

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

moazzen@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of coenzyme Q10 supplementation on glycemic control, inflammatory markers, lipid profile, oxidative stress and blood pressure in type 2 diabetic patients: a placebo-controlled trial

Public title

The effect of coenzyme Q10 supplementation on the management of type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetic patients, with body mass index 20-30. Exclusion criteria: Patients with any chronic renal, hepatic and gastrointestinal disorders, using anticoagulants, lipid lowering medications and β-blockers, consumption of vitamin-mineral supplements,

following specific diets and smokers. In the case of decreasing or increasing the blood glucose lowering medications the patient will be excluded from the study.

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Since the samples are selected by the researcher, this is a single blind study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand St.

City
Shiraz

Postal code
1978-71345

Approval date
2012-07-15, 1391/04/25

Ethics committee reference number
CT-91-6088

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
fasting blood sugar

Timepoint
at the beginning of intervention, at the end of intervention

Method of measurement
BT 1500 autoanalyzer, unit: mg/dl

2

Description
hemoglobin A1c

Timepoint
at the beginning of intervention, at the end of intervention

Method of measurement
HPLC method, will be reported as percentage

3

Description
insulin

Timepoint
at the beginning of intervention, at the end of intervention

Method of measurement
ELISA method, unit: µIU/ml

4

Description
insulin resistance

Timepoint
at the beginning of intervention, at the end of intervention

Method of measurement
according to the formula

5

Description
high-sensitivity C-reactive protein

Timepoint
at the beginning of intervention, at the end of intervention

Method of measurement
ELISA method, unit: ng/ml

6

Description
adiponectin

Timepoint
at the beginning of intervention, at the end of intervention

Method of measurement
ELISA method, unit: µg/ml

7

Description
triglyceride
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
BT-1500 autoanalyzer, unit: mg/dl

8

Description
total cholesterol
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
BT-1500 autoanalyzer, unit: mg/dl

9

Description
LDL- cholesterol
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
BT-1500 autoanalyzer, unit: mg/dl

10

Description
HDL- cholesterol
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
BT-1500 autoanalyzer, unit: mg/dl

11

Description
malondialdehyde
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
spectrophotometry, unit: µmol/l

12

Description
blood pressure
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
mercury sphygmomanometer, unit: mmHg

Secondary outcomes

1

Description
hip circumference
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
measuring with a tape measure, unit: centimeter

2

Description
weight
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
analog scale, unit: kg

3

Description
Body Mass Index
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
according to the formula, unit: kg/m2

4

Description
waist circumference
Timepoint
at the beginning of intervention, at the end of intervention
Method of measurement
measuring with a tape measure, unit: centimeter

Intervention groups

1

Description
coenzyme Q10 capsule, 100 mg, twice per day, for eight weeks, edible. Health Burst brand
Category
Other

2

Description
Cellulose acetate, 100 mg, two capsules per day, for eight weeks, edible, made in Shiraz School of Pharmacy
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Health Care Center
Full name of responsible person
Mahsa Moazen
Street address
Modares Blvd.
City
Shiraz

2

Recruitment center
Name of recruitment center
Abalfazl Health Care Center
Full name of responsible person
Mahsa Moazen
Street address
next to the Abalfazl mosque, Kolbeh Saadi
City
Shiraz

3

Recruitment center
Name of recruitment center
Hosseinebneali Health Care Center
Full name of responsible person
Mahsa Moazen
Street address
Ferdosi St.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahmodini
Street address
Central building of Shiraz University of Medical Sciences, Zand St.
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mahsa Moazen
Position
MSc student of nutrition
Other areas of specialty/work
Street address
Nutrition Department, School of Health and Nutrition, Shiraz University of Medical Sciences
City
Shiraz
Postal code
Phone
+98 71 1725 1001
Fax
Email
moazzen@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Zohreh Mazloom
Position
Associate professor
Other areas of specialty/work
Street address
Nutrition department, School of Health and Nutrition, Shiraz University of Medical Sciences
City
Shiraz
Postal code
Phone
+98 71 1725 1001
Fax
Email
zohreh.mazloom@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahsa Moazen
Position
MSc student of nutrition
Other areas of specialty/work
Street address

Nutrition Department, School of Health and Nutrition, Shiraz University of Medical Sciences
City
Shiraz
Postal code
71645111
Phone
+98 71 1725 1001
Fax
Email
moazzen@sums.ac.ir
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