

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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: μ IU/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: μ g/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: $\mu\text{mol/l}$

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/m^2

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