# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jun 2026

## Effects of coenzyme Q10 on paraxonase, total antioxidant capacity, malondialdehyde, hs-CRP, lipid profile and glycemic control in patients with type 2 diabetes

## Protocol summary


**Summary**

Coenzyme Q10 is a lipophilic antioxidant. Studies have shown that its serum levels decrease in patients with diabetes. The objective of this study is to assess effects of coenzyme Q10 as an adjunctive treatment to hypoglycemic agents on oxidative stress, lipid peroxidation, glycemic control and inflammatory markers in patients with type 2 diabetes mellitus. Fifty patients with type 2 diabetes will be randomly allocated to receive daily either 150 mg coenzyme Q10 or a placebo for 12 weeks. Patients will be referred from Institute of Endocrinology and Metabolism, Iran University of Medical Sciences. Ten-milliliter fasting blood samples will be taken at the beginning and at the end of study. Serum paraoxonase activity, total antioxidant capacity, malondialdehyde, hs-CRP, TG, TC, LDL, HDL, FBS, insulin and HbA1C will be determined in the blood samples. Weight, height and blood pressure will be measured at the beginning and at the end of the study. Food intake and physical activity will be assessed at baseline and after weeks 4, 8 and 12. For analysis of data paired sample t-test and independent t-test will be used. .


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138806102394N1**
Registration date: **2011-04-24, 1390/02/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2011-04-24, 1390/02/04

**Registrant information**


**Name**

Shima Jazayeri

**Name of organization / entity**

Iran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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+98 21 8670 4805

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sjazayeri@razi.tums.ac.ir


**Recruitment status**

**Recruitment complete**


**Funding source**

Vice-chancellor for research, Tehran University of Medical Sciences


**Expected recruitment start date**

2009-11-06, 1388/08/15

**Expected recruitment end date**

2010-05-05, 1389/02/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of coenzyme Q10 on paraxonase, total antioxidant capacity, malondialdehyde, hs-CRP, lipid profile and glycemic control in patients with type 2 diabetes

**Public title**

Effects of coenzyme Q10 on paraxonase, total antioxidant capacity, malondialdehyde, hs-CRP, lipid profile and glycemic control in patients with type 2 diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1- Patients with type 2 diabetes 2- Willing to participate 3- Duration of type 2 diabetes > 1 year 4- HbA1c<9% 5-TG<400 mg/dL \ Exclusion criteria: 1-BMI>40 2- Past history of MI or stroke 3-Patients with any of the following conditions: liver disease, kidney disease, or thyroid disease 4-Supplement use for at least 8 weeks before intervention till the end of study 5-Treatment with warfarin 6-BP>160/90 7-Pregnancy and lactation 8-Compliance<70% 9-Change in type or dose of medication for at least 8 weeks before intervention till the end of study 10-Treatment with insulin

**Age**

From **40 years** old to **75 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**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**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran

**City**

Tehran

**Postal code**

**Approval date**

2027-12-31, 1406/10/10

**Ethics committee reference number**

2155/5پ/26/د

## Health conditions studied

### 1

**Description of health condition studied**

type 2 diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

**Description**

paraxonase

**Timepoint**

before intervention, 12 weeks after intervention

**Method of measurement**

spectrophotometry

### 2

**Description**

Total antioxidant capacity

**Timepoint**

before intervention, 12 weeks after intervention

**Method of measurement**

FRAP

### 3

**Description**

MDA

**Timepoint**

before intervention, 12 weeks after intervention

**Method of measurement**

spectrophotometry

### 4

**Description**

Hs-CRP

**Timepoint**

before intervention, 12 weeks after intervention

**Method of measurement**

turbidometry

### 5

**Description**

triglyceride

**Timepoint**

before intervention, 12 weeks after intervention

**Method of measurement**

Gop-PAP

### 6

**Description**

TC

**Timepoint**

before intervention, 12 weeks after intervention

**Method of measurement**

enzymatic

**7**

**Description**
LDL
**Timepoint**
before intervention, 12 weeks after intervention
**Method of measurement**
Friedewald formula

**8**

**Description**
HDL
**Timepoint**
before intervention, 12 weeks after intervention
**Method of measurement**
precipitation

**9**

**Description**
HbA1c
**Timepoint**
before intervention, 12 weeks after intervention
**Method of measurement**
chromatography

## Secondary outcomes

**1**

**Description**
Insuline
**Timepoint**
before intervaention, 12 weeks after intervention
**Method of measurement**
RIA

**2**

**Description**
FBS
**Timepoint**
before intervaention, 12 weeks after intervention
**Method of measurement**
enzymatic

## Intervention groups

**1**

**Description**
Intervention group will receive daily 150 mg CoQ10 as three divided doses for 12 weeks. Each capsule consists of 50 mg CoQ10.
**Category**
Treatment - Other

**2**

**Description**
Placebo group will receive daily three capsules containing corn flour for12 weeks.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Institute of Endocrinology and Metabolism, Firouzgar Hospital, Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Iraj Heidari
**Street address**
**City**
Terhran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice-chancellor for research, Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Akbar Fotouhi
**Street address**
Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice-chancellor for research, Tehran 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**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Department of Nutrition, School of Public Health, Teharn University of Medical Sciences

**Full name of responsible person**
Shima Jazayeri

**Position**
Assisstant Professor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

## 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*