

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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)

##### Phone

+98 21 8670 4805

##### Email address

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 for 12 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**

Tehran

## **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,  
Tehran University of Medical Sciences

**Full name of responsible person**

Shima Jazayeri

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

#60 Alvand Street, Argantin Square

**City**

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**Postal code****Phone**

+98 21 8877 9118

**Fax****Email**

sh\_jazayeri@tums.ac.ir

### Web page address

## 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*