

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Effects of Q10 supplementation on serum levels of gamma glutamyl transferase, pseudo cholinesterase, bilirubin, ferritin and C-reactive protein in patients with type II diabetes

#### Protocol summary

##### Summary

**Objectives:** The aim of this study is to determine the Effects of Q10 supplementation on serum some biochemical variables in patients with type 2 diabetes. **Design:** In this double blind study, a total number of 70 patients will be selected. They will be divided into two groups of intervention (coenzyme Q10) and control (placebo) by simple random sampling. They will be matched in age and BMI. The endocrinologist, pharmacy and the participants will be blinded to the study interventions. **Setting and conduct:** The aim and procedures of the study will be conveyed to the participants and written informed consent will be obtain from each of them. **Major Inclusion and Exclusion criteria:** Major inclusion criteria are Type 2 diabetic patients for more than 2 years and not consumption of vitamin and mineral supplements during the last three months. Major Exclusion criteria are changing in dosage of glucose lowering medications, physical activity and diet during the intervention. **Intervention:** One group will receive coenzyme Q10 (one 100 mg capsule for 12 weeks) and the other group will receive placebo capsule containing cellulose acetate for the same dosage and period. **Main outcome measures (variables):** Serum levels of glucose, hemoglobin A1c, insulin, cholesterol, triglyceride, HDL-C, LDL-C, hs-CRP, Q10, gamma glutamyl transferase, pseudo cholinesterase, bilirubin and ferritin will be measured at the beginning and at the end of the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011125949N1**

Registration date: **2016-01-30, 1394/11/10**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-01-30, 1394/11/10

##### Registrant information

###### Name

Ali Khosrowbeygi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3638

###### Email address

a.khosrowbeygi@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2016-03-01, 1394/12/11

##### Expected recruitment end date

2016-07-02, 1395/04/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Q10 supplementation on serum levels of gamma glutamyl transferase, pseudo cholinesterase, bilirubin, ferritin and C-reactive protein in patients with type II diabetes

##### Public title

Benefits of Q10 supplementation in patients with type II diabetes

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Type 2 diabetic patients for more than 2 years and not consumption of vitamin and mineral supplements during the last three months. Exclusion criteria: changing in dosage of glucose lowering medications; physical activity and diet during the intervention; any chronic renal; hepatic; thyroid; haematic and gastrointestinal disorders; using anticoagulants; diuretics and  $\beta$  blockers; hormone therapy; insulin therapy; alcoholism; smoking; pregnancy and lactation.

### **Age**

From **30 years** old to **65 years** old

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **70**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

Randomization will be done using simple random sampling method.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

##### **Street address**

Sardasht, Arak University of Medical Sciences, Arak

##### **City**

Arak

##### **Postal code**

#### **Approval date**

2015-12-21, 1394/09/30

#### **Ethics committee reference number**

IR.ARAKMU.REC.1394.251

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Type 2 diabetic

#### **ICD-10 code**

E11

#### **ICD-10 code description**

Non-insulin-dependent diabetes mellitus

## **Primary outcomes**

### **1**

#### **Description**

Fasting glucose

#### **Timepoint**

Before and after 12 weeks of intervention

#### **Method of measurement**

Colorimetric

### **2**

#### **Description**

Fasting insulin

#### **Timepoint**

Before and after 12 weeks of intervention

#### **Method of measurement**

ELISA

### **3**

#### **Description**

HbA1C

#### **Timepoint**

Before and after 12 weeks of intervention

#### **Method of measurement**

Chromatography

### **4**

#### **Description**

HDL-C

#### **Timepoint**

Before and after 12 weeks of intervention

#### **Method of measurement**

Colorimetric

### **5**

#### **Description**

TG

#### **Timepoint**

Before and after 12 weeks of intervention

#### **Method of measurement**

Colorimetric

### **6**

#### **Description**

TC

#### **Timepoint**

Before and after 12 weeks of intervention  
**Method of measurement**  
Colorimetric

## 7

**Description**  
LDL-C  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
Friedewald's equation

## 8

**Description**  
Q10  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
Chromatography

## 9

**Description**  
Gamma glutamyl transferase  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
Colorimetric

## 10

**Description**  
Bilirubin  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
Colorimetric

## 11

**Description**  
Ferritin  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
ELISA

## 12

**Description**  
hs-CRP  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
ELISA

## 13

**Description**  
Pseudo cholinesterase  
**Timepoint**  
Before and after 12 weeks of intervention

**Method of measurement**  
Colorimetric

## **Secondary outcomes**

### 1

**Description**  
Blood pressure  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
Barometer

### 2

**Description**  
waist circumference  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
tape measure

### 3

**Description**  
BMI  
**Timepoint**  
Before and after 12 weeks of intervention  
**Method of measurement**  
Formula

## **Intervention groups**

### 1

**Description**  
One capsule coenzyme Q10 (100 mg) per day for 12 weeks.  
**Category**  
Treatment - Drugs

### 2

**Description**  
One capsule placebo cellulose acetate (100 mg) per day for 12 weeks.  
**Category**  
Placebo

## **Recruitment centers**

### 1

**Recruitment center**  
**Name of recruitment center**  
Amiralmomenin Hospital  
**Full name of responsible person**  
Mahsa Gholami  
**Street address**  
Basij Square, Sardasht, Amiralmomenin Hospital, Arak  
**City**

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ali Ghazavi

**Street address**

Basij Square, Sardasht, Arak University of Medical Sciences, Arak

**City**

Arak

**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 of Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ali Khosrowbeygi

**Position**

PhD

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

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## Person responsible for scientific inquiries

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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*