

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 β 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**

Basij Square, Sardasht, Department of Biochemistry, School of Medicine, Arak University of Medical Sciences, Arak

City

Arak

Postal code**Phone**

+98 86 3417 3501

Fax**Email**

a.khosrowbeygi@arakmu.ac.ir;

khosrowbeygi@yahoo.com

Web page address

Person responsible for scientific 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**

Basij Square, Sardasht, Department of Biochemistry, School of Medicine, Arak University of Medical Sciences, Arak

City

Arak

Postal code**Phone**

+98 86 3417 3501

Fax**Email**

a.khosrowbeygi@arakmu.ac.ir;

khosrowbeygi@yahoo.com

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