

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of coenzyme Q10 supplementation on serum adiponectin-to-leptin ratio, 8-isoprostane and malondialdehyde in female patients with type 2 diabetes

Protocol summary

Summary

Objectives: The aim of this study is to determine the effects of Q10 supplementation on serum biochemical variables in patients with type 2 diabetes. **Design:** In this double blind study a total number of 68 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 obtained from each of them. **Major Inclusion and Exclusion criteria:** Major inclusion criteria are patients with type 2 diabetic 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 with the same dosage and period. **Main outcome measures (variables):** Serum levels of glucose, hemoglobin A1c, insulin, leptin, adiponectin, 8-isoprostane malodialdehyde will be measured at the beginning and at the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081525949N3**
Registration date: **2016-08-27, 1395/06/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-27, 1395/06/06

Registrant information

Name

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Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-07-26, 1395/05/05

Expected recruitment end date

2016-10-26, 1395/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of coenzyme Q10 supplementation on serum adiponectin-to-leptin ratio, 8-isoprostane and malondialdehyde in female patients with type 2 diabetes

Public title

Effects of Q10 supplementation in type II diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients that have been suffered type 2 diabetes for more than 2 years and that have not consumed 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; hormone therapy; insulin therapy; alcoholism; smoking; pregnancy; lactation and using anticoagulants, diuretics and β blockers.

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: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The patients will be divided into intervention and control groups by simple random sampling.

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

2016-07-25, 1395/05/04

Ethics committee reference number

IR.ARAKMU.REC.1395.158

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

HbA1C

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Chromatography

3

Description

Fasting insulin

Timepoint

Before and after 12 weeks of intervention

Method of measurement

ELISA

4

Description

Coenzyme Q10

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Chromatography

5

Description

Leptin

Timepoint

Before and after 12 weeks of intervention

Method of measurement

ELISA

6

Description

Adiponectin

Timepoint

Before and after 12 weeks of intervention

Method of measurement

ELISA

7

Description

8-isoprostane

Timepoint

Before and after 12 weeks of intervention

Method of measurement

ELISA

8

Description

Malondialdehyde

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Spectrophotometric

Secondary outcomes

1

Description

BMI

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Formula

Intervention groups

1

Description

Control group: One capsule placebo cellulose acetate (100 mg) per day for 12 weeks.

Category

Placebo

2

Description

Intervention group: One capsule coenzyme Q10 (100 mg) per day for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Parvin Zaree

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

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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