

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of coenzyme Q10 supplementation on serum amylase ,adenosine deaminase, catalase, antioxidant capacity and lipid ratios in patients with type 2 diabetes

Protocol summary

Summary

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 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, Q10, amylase, adenosine deaminase, catalase and antioxidant capacity will be measured at the beginning and at the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011325949N2**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

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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

2016-02-20, 1394/12/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of coenzyme Q10 supplementation on serum amylase ,adenosine deaminase, catalase, antioxidant capacity and lipid ratios in patients with type 2 diabetes

Public title

Effect of coenzyme Q10 supplementation on some biochemical factors in 2 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; acute and chronic pancreatitis; tuberculosis; 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: **68**

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

Basij Sq., Sardasht,

City

Arak

Postal code

Approval date

2015-12-21, 1394/09/30

Ethics committee reference number

IR.ARAKMU.REC.1394.250

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

TG

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Colorimetric

5

Description

TC

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Colorimetric

6

Description

HDL-C

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

Amylase

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Colorimetric

9

Description

Adenosine deaminase

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Colorimetric

10

Description

Catalase

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Spectrophotometric

11

Description

Antioxidant capacity

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Colorimetric

12

Description

Q10

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Chromatography

13

Description

Lipid ratios

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Formula

14

Description

Insulin sensitivity

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Formula

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

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

Category

Treatment - Drugs

2

Description

Control group: One capsule placebo cellulose acetate (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
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Basij Sq., Sardasht
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Web page address

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 Sq., Sardasht
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
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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