Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 for12 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
Terhran

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, Teharn University of Medical Sciences

Full name of responsible person
Shima Jazayeri

Position
Assisstant Professor

Other areas of specialty/work

Street address
#60 Alvand Street, Argantin Square

City
Tehran

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