Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of CoQ10 supplementation on neuropathic symptoms, blood glucose and some inflammatory and antioxidant parameters in patients with type 2 diabetes

Protocol summary

Summary

In this double blind randomized controlled trial, we investigate the effects of coenzyme Q10 on neuropathic symptoms, blood Glucose, insulin, hsCRP, and TAC (Total antioxidant capacity) in type two diabetes. In this study 70 diabetic patients with neuropathic symptoms which have been recognized by using the Michigan Questionnaire and examination of nerve reflexes will be recruited from Yazd Diabetes Research Center. The patients will be randomly divided into two groups to receive daily either 200 mg CoQ10 (divided dose) or placebo (edible microcrystal cellulose) for 12 weeks. NCS (Nerve Conduction Study) will be assessed by using The Electromyography Method at onset and at the end of the study. For biochemical analysis 8ml of blood will be collected at the beginning and at the end of the trial. During the intervention period, individuals consume their usual diet and medicine. After collecting the data, they will be coded and analyzed in the SPSS program.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109127541N1**
Registration date: **2011-10-27, 1390/08/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-27, 1390/08/05

Registrant information

Name

Maryam Akbari

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 34 5423 2517

Email address

maryamakbari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-06-19, 1391/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of CoQ10 supplementation on neuropathic symptoms, blood glucose and some inflammatory and antioxidant parameters in patients with type 2 diabetes

Public title

The effect of CoQ10 supplementation on some complications of type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1.The agreement of the patients to contribute in the trial; 2. patients that have type two diabetes for at least 5 years; 3.The patients should have

neuropathy symptoms that have been recognized by a physician (The patients' score on the Michigan score should be at least 8 and their nerve reflexes should be weak); 4.The patients should not have any other neurologic, kidney or hepatic diseases; 5.If the patients take medicine for neuropathy, the dosage of their medicine should not change during the trial; 6.If the patients have not taken a medicine at the beginning of the trial, they should not start taking it during the trial; 7.The patients should not have taken antioxidant supplements from the past 3 months. Exclusion criteria 1.If a dosage of a patient's medicine changes that patient will be excluded from the trial; 2.If a patient who has not taken any medicine for his neuropathy starts to take a medicine during the trial that patient will be excluded from the trial; 3.Pregnancy and lactation.

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadoughi University of Medical Sciences and Health Services

Street address
Daneshju Blvd, Imam Hossein sq

City
Yazd

Postal code

Approval date
2011-03-16, 1389/12/25

Ethics committee reference number
17/1/39322/پ

Health conditions studied

1

Description of health condition studied
Type II Diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Michigan score

Timepoint
before intervention, 12 weeks after intervention

Method of measurement
Michigan neuropathy screening instrument

2

Description
hs-CRP

Timepoint
before intervention, 12 weeks after intervention

Method of measurement
Elisa

3

Description
TAC (Total antioxidant capacity)

Timepoint
before intervention, 12 weeks after intervention

Method of measurement
Elisa

4

Description
FBS (fasting blood glucose)

Timepoint
before intervention, 12 weeks after intervention

Method of measurement
glucose oxidase method

5

Description
Fasting Insulin

Timepoint
before intervention, 12 weeks after intervention

Method of measurement
Elisa

6

Description
Insulin Resistance

Timepoint

before intervention, 12 weeks after intervention
Method of measurement
Homeostasis Model Assessment of Insulin Resistance, HOMA-IR

7

Description
sensitivity to insulin
Timepoint
before intervention, 12 weeks after intervention
Method of measurement
HOMA Calculator for excel ver 2.2 (diabetes trials unit university of oxford)

8

Description
the secretion function of the Pancreas's β cells
Timepoint
before intervention, 12 weeks after intervention
Method of measurement
HOMA Calculator for excel ver 2.2 (diabetes trials unit university of oxford)

Secondary outcomes

1

Description
NCS (Nerve conduction study)
Timepoint
before intervention, 12 weeks after intervention
Method of measurement
Electromyography device

Intervention groups

1

Description
The intervention group will take 100 mg CoQ10 capsules twice a day for 3 months
Category
Treatment - Drugs

2

Description
The control group will take 100 mg placebo (edible microcrystalin celulose) capsules twice a day for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Diabetes Research Center
Full name of responsible person
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences and Health Services
Full name of responsible person
Azadeh Nadjarzadeh
Street address
Daneshju Blvd
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi University of Medical Sciences and Health Services
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
Shahid Sadoughi University of Medical Sciences and Health Services
Full name of responsible person
Maryam Akbari
Position
student
Other areas of specialty/work
Street address
Behdasht Faculty, Daneshju Blvd
City
Yazd
Postal code
Phone
+98 35 1724 9333
Fax
Email
maryamakbari_f@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Sadoughi University of Medical Sciences and Health Services

Full name of responsible person
Dr. Azadeh Nadjarzadeh

Position
PHD of Nutrition and Diet Therapy

Other areas of specialty/work

Street address
Behdasht Faculty, Daneshju Blvd

City
Yazd

Postal code

Phone
+98 35 1724 9333

Fax

Email
azadehnajarzadeh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Sadoughi University of Medical Sciences and Health Services of Yazd

Full name of responsible person
Maryam Akbari

Position
student

Other areas of specialty/work

Street address
Daneshju Blvd

City
Yazd

Postal code

Phone

Fax

Email

Web page address

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