

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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##### 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  $\beta$  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 microcrystallin cellulose) 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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Position**

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**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*