

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### The effect of Q10 supplementation on metabolic profile, inflammatory marker and oxidative stress in diabetic hemodialysis patients

#### Protocol summary

##### Summary

Objective: The aim of this study is to determine the effects of coenzyme Q10 supplementation on metabolic inflammation profile and oxidative stress in diabetic hemodialysis patients. Study design: parallel double-blind (both patients and researchers) randomized controlled clinical trial. Inclusion criteria: 1- hemodialysis patients with glomerular filtration rate less than 10 or 25 ml/min with malnutrition and hypercalemy. 2- aged 45-75. 3- average blood pressure (systolic pressure 140-160 mmHg, diastolic pressure 90-100 mmHg) 4-diabetic patients according to American diabetes association criteria. Exclusion criteria: 1-unwilling to cooperate 2-hyperthyroidism and hypothyroidism 3-specific disease leading to bed. 4-malignant hypertension (systolic pressure more than 160 mmHg and diastolic pressure more than 100mmHg) Population and sample size: 70 diabetic hemodialysis patients of eligible and referred to Akhavan Clinic affiliated to Kashan University of Medical Science, Kashan, Iran in the study will be selected. Intervention: patients will be assigned to receive either coenzyme Q10 (n=35) or placebo (n=35). Coenzyme Q10 and placebo capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after intervention. At the beginning and end of the intervention: 12 weeks. Outcome: Insulin metabolism markers (primary outcome) and lipid inflammation profiles and oxidative stress (secondary outcome) at study baseline and end-of-trial.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081811763N30**

Registration date: **2017-01-24, 1395/11/05**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-01-24, 1395/11/05

##### Registrant information

###### Name

Gholamreza Askari

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2110

###### Email address

askari@mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Esfahan University of Medical Science

##### Expected recruitment start date

2017-02-05, 1395/11/17

##### Expected recruitment end date

2017-03-07, 1395/12/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Q10 supplementation on metabolic profile, inflammatory marker and oxidative stress in diabetic hemodialysis patients

##### Public title

effect of supplementation in treatment of diabetic hemodialysis patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

1- hemodialysis patients with glomerular filtration rate less than 10 or 25 ml/min with malnutrition and hypercalemy. 2- aged 45-75. 3-average blood pressure (systolic pressure 140-160 mmHg , diastolic pressure 90-100 mmHg) 4-diabetic patients according to American diabetes association criteria. Exclusion criteria: 1- unwilling to cooperate 2- hyperthyroidism and hypothyroidism 3-specific disease leading to bed. 4- malignant hypertension (systolic pressure more than 160 mmHg and diastolic pressure more than 100mmHg)

## Age

From **45 years** old to **75 years** old

## Gender

Both

## Phase

N/A

## 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

Isfahan University of Medical Sciences

##### Street address

hezarjarib street, Isfahan University of Medical Sciences

##### City

Isfahan

##### Postal code

#### Approval date

2016-12-25, 1395/10/05

#### Ethics committee reference number

IR.MUI.REC.1395.1.109

## Health conditions studied

### 1

#### Description of health condition studied

hemodialysis

#### ICD-10 code

N18

#### ICD-10 code description

Chronic kidney disease

## Primary outcomes

### 1

#### Description

Insulin

#### Timepoint

At the beginning of the study and after 3 month intervention

#### Method of measurement

ELISA kit - µIU/ml

### 2

#### Description

Fasting blood sample

#### Timepoint

At the beginning of the study and after 3 month intervention

#### Method of measurement

ensymatic - mg/dl

### 3

#### Description

HOMA-IR

#### Timepoint

At the beginning of the study and after 3 month intervention

#### Method of measurement

calculation

### 4

#### Description

QUICKI

#### Timepoint

At the beginning of the study and after 3 month intervention

#### Method of measurement

calculation

### 5

#### Description

HOMA-B

#### Timepoint

At the beginning of the study and after 3 month intervention

#### Method of measurement

calculation

## **6**

### **Description**

HbA1C

### **Timepoint**

At the beginning of the study and after 3 month intervention

### **Method of measurement**

calculation - percentage

## **Secondary outcomes**

## **1**

### **Description**

Nitric oxide

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

Spectrophotometry

## **2**

### **Description**

hs-CRP

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

ELISA kit

## **3**

### **Description**

TAC

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

Spectrophotometry

## **4**

### **Description**

GSH

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

Spectrophotometry

## **5**

### **Description**

HDL

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

Ensymatic

## **6**

### **Description**

Cholestrol

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

Ensymatic

## **7**

### **Description**

TG

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

Ensymatic

## **8**

### **Description**

MDA

### **Timepoint**

At the beginning of the study and after 3 month of intervention

### **Method of measurement**

Spectrophotometry

## **Intervention groups**

## **1**

### **Description**

60 mg coenzyme Q10, twice a day, for 3 month orally

### **Category**

Treatment - Drugs

## **2**

### **Description**

Placebo, twice a day, for 3 month orally

### **Category**

Placebo

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Akhavan clinic

#### **Full name of responsible person**

Alireza soleimani

#### **Street address**

#### **City**

Kashan

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Gholamreza Askari

**Street address**

Isfahan, Hezarjarib Street, Isfahan University of Medical Sciences

**City**

Isfahan

**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, Isfahan 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**

Kashan University of Medical Science

**Full name of responsible person**

Zatollah Asemi

**Position**

PHD of Nutrition

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### Person responsible for scientific inquiries

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### Person responsible for updating data

**Contact****Name of organization / entity**

Isfahan University of Medical Science

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Melika Fallah

**Position**

msc student

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### 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*