

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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 placebos 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)

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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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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