Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 assossiation 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

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Gholamreza Askari
Name of organization / entity
Isfahan University of Medical Sciences
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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 assossiation 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 - µlU/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

Other areas of specialty/work

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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