

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Clinical trial of the effect of coenzyme Q10 supplementation compared with the placebo on gene expression involved in insulin, lipid and inflammation signaling pathway in patients with diabetic nephropathy

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of coenzyme Q10 supplementation on gene expression involved in insulin, lipid and inflammation signaling pathway in patients with diabetic nephropathy.

Design

Randomized, double-blind, placebo-controlled clinical trial, phase 3, 40 patients

Settings and conduct

40 patients with diabetic nephropathy of eligible and referred to Naghavi Clinic, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic nephropathy and aged 40 to 85 years will be included in this study.

Exclusion criteria: Consumption of any nutritional supplements within 3 months, history of active infection within 3 months, history of hospital admission within 3 months, malignancy and/or liver cirrhosis, subjects with uncontrolled diabetes, pregnant women.

Intervention groups

Intervention group: 100 mg coenzyme Q10 (Nature, New York, USA), once a day, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.

Main outcome variables

Outcomes: Gene expression involved in insulin (primary outcomes), and lipid and inflammation (secondary outcomes) signaling pathway will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201611155623N93**

Registration date: **2016-11-22, 1395/09/02**

Registration timing: **retrospective**

Last update: **2019-10-01, 1398/07/09**

Update count: **1**

Registration date

2016-11-22, 1395/09/02

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2015-12-06, 1394/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of coenzyme Q10

supplementation compared with the placebo on gene expression involved in insulin, lipid and inflammation signaling pathway in patients with diabetic nephropathy

Public title

Effect of supplementation in treatment of patients with diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic nephropathy Aged 40 to 80 years

Exclusion criteria:

Consumption of any nutritional supplements within 3 months
History of active infection within 3 months
History of hospital admission within 3 months
Malignancy and/or liver cirrhosis
Subjects with uncontrolled diabetes
Pregnant women

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI and age. Then, participants in each block will be randomly allocated into two treatment groups to take either supplement or placebo. Randomization will be done by the use of Stat Trek software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic in Kashan who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2015-11-05, 1394/08/14

Ethics committee reference number

IR.Kaums.REC.1394.106

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

N08.3

ICD-10 code description

Glomerular disorders in diabetes mellitus (E10-E14 with common fourth character .2+)

Primary outcomes

1

Description

Expressed levels of PPAR- γ

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

2

Description

Expressed levels of GLUT-1

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

Secondary outcomes

1

Description

Expressed levels of Lp(a) gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

2

Description

Expressed levels of LL-1 gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

3

Description

Expressed levels of LL-8 gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

4

Description

Expressed levels of TNF-a gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

5

Description

Expressed levels of ox-LDL gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

6

Description

Expressed levels of TGF-B gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: 100 mg coenzyme Q10 (Nature, New York, USA), once a day, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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, Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available