Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of Q10 supplementation on insulin resistance, inflammatory factors and biomarkers of oxidative stress in type 2 diabetes with Coronary Heart Disease

Protocol summary

Study aim

The aim of this study is to determine the effects of Q10 supplementation on metabolic profiles, inflammatory factors and biomarkers of oxidative stress among type 2 diabetes patients with coronary heart disease (CVD).

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 60 subjects with CVD eligible and referred to Outpatient Cardiology Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Overweight patients aged 40-85 years old and diagnosed with type 2 diabetes and coronary heart disease. Exclusion Criteria: Intake of CoQ10 or antioxidant supplements within the last 3 months, acute myocardial infarction within the past 3 months, cardiac surgery within the past 3 months and renal or liver failure.

Intervention groups

Intervention: Patients will be assigned to receive either 100 mg Q10 supplements (intervention group: n=30) or placebo (control group: n=30). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure metabolic profiles, inflammatory factor and biomarkers of oxidative stress. Start and End Date of Intervention: 8 weeks

Main outcome variables

Outcomes: Glucose homeostasis parameters and hs-CRP (primary outcomes), and lipid and metabolic profiles (secondry outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201502245623N35**
Registration date: **2015-03-06, 1393/12/15**
Registration timing: **retrospective**

Last update: **2019-10-18, 1398/07/26**
Update count: **1**

Registration date

2015-03-06, 1393/12/15

Registrant information

Name
Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2015-03-04, 1393/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Q10 supplementation on insulin resistance, inflammatory factors and biomarkers of oxidative stress in type 2 diabetes with Coronary Heart Disease

Public title

Effect of supplementation in treatment of type 2 diabetes with Coronary Heart Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects aged 45-75 years Diagnosed with type 2 diabetes and CVD

Exclusion criteria:

Intake of CoQ10 or antioxidant supplements within the last 3 months Acute myocardial infarction within the past 3 months Cardiac surgery within the past 3 months Renal or liver failure

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to receive Q10 (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Approval date

2015-02-28, 1393/12/09

Ethics committee reference number

93193

Health conditions studied

1

Description of health condition studied

بیماری کرونر قلبی

ICD-10 code

I25.9

ICD-10 code description

Ischaemic heart disease (chronic)

Primary outcomes

1

Description

Fasting plasma glucose

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic

2

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

3

Description

Hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

4

Description
Insulin resistance
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

Secondary outcomes

1

Description
Triglycerides
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
Total cholesterol
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total antioxidant
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Glutathione
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Nitric oxide
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
VLDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
LDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Q10 tablet, 100 mg, daily, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, daily, for 8 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Outpatient Cardiology Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
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research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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