Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Ubiquinone on inflammation and oxidative stress status among type 2 diabetes patients with coronary heart disease

Protocol summary

Summary

Objectives: Determining the effect of ubiquinone on inflammation and oxidative stress status among type 2 diabetes patients with coronary heart disease. Design: Parallel double-blind randomized controlled clinical trial.Inclusion Criteria: Subjects with 45-75 years old، diagnosed with type 2 diabetes with coronary heart disease . Exclusion Criteria:Patients who do not want to cooperate؛ diabetic patients who have others complications associated with diabetes such as: kidney disease؛ neuropathy and retinopathy؛ patients with hypo and/or hyperthyroidism are excluded from this study. Population and sample size: 60 subjects with coronary heart disease, eligible and referred to Shahid Beheshti hospital affiliated to Kashan University of Medical Sciences, Kashan, Iran. in the study will be selected. 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 evaluate lipoprotein a (Lp(a)), status of inflammation and oxidative stress. Start and End Date of Intervention: 8 weeks (May 4, 2015-Jul 5, 2015). Outcomes: Advance glycation End Products (AGEs), Inflamatory Factor IL-9, status of oxidative stress such as Protein carbonyl, and MDA will be measured at baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111920007N1**
Registration date: **2015-06-09, 1394/03/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-09, 1394/03/19

Registrant information

Name
Seyyed Mehdi Mirhashemi
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
Phone
+98 31 5562 0608
Email address
mirhashemi@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical SciencesKashan University of Medical Sciences,

Expected recruitment start date

2015-05-04, 1394/02/14

Expected recruitment end date

2015-05-10, 1394/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ubiquinone on inflammation and oxidative stress status among type 2 diabetes patients with coronary heart disease

Public title

Effect of Ubiquinone on diabetes with coronary heart disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Subjects with 45-75 years old؛ diagnosed with type 2 diabetes with coronary heart disease . Exclusion Criteria:Patients who do not want to corporate؛ Diabetic patients who have others complications associated with diabetes such as: kidney disease؛ neuropathy and retinopathy؛ Patients with hypo and/or hyperthyroidism are excluded from this study.

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomized Numbers Table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan Unversity of Medical Sciences

Street address
5th of Qotb –e Ravandi Blvd

City
Kashan

Postal code

Approval date
2015-04-26, 1394/02/06

Ethics committee reference number
KAUMS.REC.1394.001

Health conditions studied

1

Description of health condition studied
Chronic ischaemic heart disease

ICD-10 code
I25.9

ICD-10 code description
Chronic ischaemic heart disease

Primary outcomes

1

Description
Advanced gylcation end Products (AGEs)

Timepoint
Before and after intervention

Method of measurement
flourimetery

2

Description
Protein carbonyl

Timepoint
before and after intervention

Method of measurement
spectrophotometer

3

Description
MDA

Timepoint
before and after of Intervention

Method of measurement
ELISA

4

Description
LP(a)

Timepoint
before and after Intervention

Method of measurement
ELISA

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Control group: Placebo, daily, 8 weeks orally

Category
Treatment - Drugs

2

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr. Seyyed Mehdi Mirhashemi
Street address
5th of Qotb –e Ravandi Blvd
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Kashan University of Medical Sciences
Full name of responsible person
Seyyed Mehdi Mirhashemi
Street address
5th of Qotb –e Ravandi Blvd,
City
Kashan
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 of Kashan 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 Sciences
Full name of responsible person
Dr. Seyyed Mehdi Mirhashemi
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Person responsible for updating data

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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