

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

2015-06-09, 1394/03/19

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), Inflammatory 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

Registrant information

Name

Seyyed Mehdi Mirhashemi

Name of organization / entity

Kashan University of Medical Sciences

Country

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 Sciences Kashan 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 participate: 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 University 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 glycation end Products (AGEs)

Timepoint

Before and after intervention

Method of measurement

flourimetry

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

Position

PhD in Clinical Biochemistry

Other areas of specialty/work

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Full name of responsible person

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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