

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effects of alpha-lipoic acid supplementation on metabolic profiles in type 2 diabetic patients with coronary heart disease

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of alpha-lipoic acid supplementation on metabolic profiles in type 2 diabetic patients with coronary heart disease (CHD).

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive alpha-lipoic acid supplements (n=30) or placebo (n=30).

Settings and conduct

Among patients with CHD referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. Intervention period: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 45-85 years diagnosed with type 2 diabetes and coronary heart disease.
Exclusion Criteria: Patients with thyroid disorders, Severe renal insufficiency, hepatic failure, Those experiencing an acute myocardial infarction within the past 3 months, Patients undergoing cardiac surgery within the past 3 months.

Intervention groups

Intervention group: Alpha-lipoic acid supplements (Support Nutrition Pharmaceutical Company, USA), 600 mg, daily, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) daily for 12 weeks orally

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles and inflammatory markers (secondary outcomes) will be quantified at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N48**

Registration date: **2019-02-05, 1397/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-05, 1397/11/16**

Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-22, 1397/11/02

Expected recruitment end date

2019-02-21, 1397/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of alpha-lipoic acid supplementation on metabolic profiles in type 2 diabetic patients with coronary heart disease

Public title

Alpha-lipoic acid effects on coronary heart disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 45-85 years People diagnosed with type 2 diabetes and coronary heart disease.

Exclusion criteria:

Patients with thyroid disorders. Severe renal insufficiency hepatic failure Those experiencing an acute myocardial infarction within the past 3 months Patients undergoing cardiac surgery within the past 3 months

Age

From **45 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

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m²) and age (<65 and ≥65 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups.

<https://stattrek.com/statistics/random-number-generator.aspx>

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 Cardiology clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

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

8115187159

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.102

Health conditions studied**1****Description of health condition studied**

Coronary Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

Primary outcomes**1****Description**

Insulin resistance

Timepoint

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

Method of measurement

Calculation using homeostasis model of assessment insulin resistance formula

2**Description**

Fasting serum Insulin levels

Timepoint

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

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

High-density lipoprotein (HDL) cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

high-sensitivity C-reactive protein (hs-CRP)

Timepoint

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

Method of measurement

Elisa kit

5

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Alpha-lipoic acid supplements (Support Nutrition Pharmaceutical Company, USA), 600 mg, daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

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

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi 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

Full name of responsible person

Dr. Hamidreza Banafshe

Street address

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banafshe-h@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

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address**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

Nutrition

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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