

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effects of black seed 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 black seed 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 black seed supplements (n=35) or placebo (n=35).

Settings and conduct

Among patients with coronary heart disease referred to cardiology clinic, 70 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 24 weeks after the intervention. Intervention period: 24 weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 45-85 years diagnosed with type 2 diabetes and coronary heart disease. Non-inclusion 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: Four N. Sativa containing capsules (Barij Essence, Kashan, Iran), 500 mg each capsule, daily, for 24 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) daily for 24 weeks orally.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N61**

Registration date: **2019-07-22, 1398/04/31**

Registration timing: **retrospective**

Last update: **2019-07-22, 1398/04/31**

Update count: **0**

Registration date

2019-07-22, 1398/04/31

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-05, 1396/06/14

Expected recruitment end date

2018-09-05, 1397/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of black seed supplementation on metabolic profiles in type 2 diabetic patients with coronary heart disease

Public title

Black seed 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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 70 by SPSS software (version 16) and participants will be randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

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 supplements. 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 Arak University of Medical Sciences

Street address

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

1771844351

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.ARAKMU.REC.1396.196

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 24 weeks of intervention

Method of measurement

Calculation using homeostasis model of assessment insulin resistance formula

Secondary outcomes**1****Description**

Fasting serum insulin levels

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Elisa kit

2**Description**

Total cholesterol
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
High-density lipoprotein (HDL) cholesterol
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Triglycerides
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
high-sensitivity C-reactive protein (hs-CRP)
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Elisa kit

6

Description
Nitric oxide
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 24 weeks of

intervention
Method of measurement
Spectrophotometry

9

Description
Glutathione
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Four N. Sativa containing capsules (Barij Essence, Kashan, Iran), 500 mg each capsule, daily, for 24 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran) daily for 24 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology clinic
Full name of responsible person
Dr. Fariba Raygan
Street address
Ghotbe Ravandi Boulevard, Kashan
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raygan.fariba2@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of

Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

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alikalimair@yahoo.com

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, Arak 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

Dr. Fariba Raygan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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