Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 31 5546 3378

Email address

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

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5546 3378

Email

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

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

City
Arak

Province
Markazi

Postal code
1771844351

Phone
+98 86 3417 3645

Email
alikamaliir@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
Cardiology

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Email
raygan.fariba2@gmail.com

Person responsible for scientific 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
Cardiology

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Email
raygan.fariba2@gmail.com

Person responsible for updating data

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
Cardiology

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Email
raygan.fariba2@gmail.com

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