

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Black seed (*Nigella Sativa*) powder on serum glucose and Lipids level of type 2 diabetic patients

Protocol summary

Study aim

Determine the effect of black seed powder on lipid profiles and glucose in type 2 diabetes

Design

A clinical trial with a control group, a randomized, single blind study. The sample size is 80 (40 in the experimental group and 40 in the control group).

Settings and conduct

Consumption of black seed powder for 2 months in the test group and placebo capsule in the control group. The site of the study is the Imam Khomeini Hospital in Khomein. Patients are unaware of being in a test or control group.

Participants/Inclusion and exclusion criteria

Diagnosis of type 2 diabetes (based on ADA criteria), Being treated with oral hypoglycaemic drugs. exclusion criteria: En According to patients' statements, they suffer from any mental or physical illness and consume medications; be pregnant.

Intervention groups

Consumption of black seed powder in the intervention group and taking placebo capsules in the control group

Main outcome variables

blood glucose; lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170501033751N3**

Registration date: **2019-05-07, 1398/02/17**

Registration timing: **retrospective**

Last update: **2019-05-07, 1398/02/17**

Update count: **0**

Registration date

2019-05-07, 1398/02/17

Registrant information

Name

rezvan ghafarzadegan

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3426 2226

Email address

rghafarzadegan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Black seed (*Nigella Sativa*) powder on serum glucose and Lipids level of type 2 diabetic patients

Public title

Effect of Black seed (*Nigella Sativa*) powder on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years and under 60 years; at least 6 months passed from diabetes diagnosis. The patient does not have adequate glycemic control

Exclusion criteria:

According to patients' statements, they suffer from any

mental or physical illness and consume drugs; be pregnant

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

randomized allocation

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients in the test and control group are not aware of their group. They are randomly assigned to the test and control groups and are not aware of the contents of the package containing the drug or placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of khomein University of Medical Sciences

Street address

Qods Ave

City

khomein

Province

Markazi

Postal code

3881858573

Approval date

2018-10-16, 1397/07/24

Ethics committee reference number

lr.khomein.rec.1397.009

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E11

ICD-10 code description

type 2 diabetes mellitus

Primary outcomes

1

Description

blood glucose

Timepoint

Before the intervention and two months after starting the consume of Black seed (Nigella Sativa) powder

Method of measurement

Measurement of blood glucose level in the laboratory using an autoanalyzer

Secondary outcomes

1

Description

lipid profile

Timepoint

Before the intervention and two months after starting the consume of black seed powder

Method of measurement

Measurement of serum lipids levels in the laboratory using an autoanalyzer

Intervention groups

1

Description

Intervention group: Each capsule contains 500 milligrams of blackseed grains. One capsule per day orally (For two months) This capsule is manufactured by Institute of Medicinal Plants of Academic Jihad.

Category

Treatment - Drugs

2

Description

Control group: Take 500 mg capsules of placebo containing breadcrumbs. Two capsules per day orally (For three months). This capsule is manufactured by Institute of Medicinal Plants of Academic Jihad.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital in khomein

Full name of responsible person

Rezvan Ghafarzadegan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Arak University of Medical Sciences
Full name of responsible person
Rezvan Ghafarzadegan
Position

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is sharable when unrecognizable

When the data will become available and for how long

2019

To whom data/document is available

all researcher

Under which criteria data/document could be used

to related research

From where data/document is obtainable

khomein medical university

What processes are involved for a request to access data/document

one month

Comments