

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 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 capsule 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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Modarres Ave  
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rghafarzadegan@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Hamid Momeni  
**Street address**  
Modarres Ave  
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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**

Academic instructor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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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**