

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Assessing the effect of Cumin (Cuminum Cyminum L) and black seed (Nigella sativa) on glycemic control

#### Protocol summary

##### Study aim

Determining and comparing fasting blood glucose and HbA1C at baseline and end of the study between groups and intragroup before and after intervention

##### Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

##### Settings and conduct

This double blinded study will be performed in Fayaz Bakhsh Hospital. Before study initiation demographic information, clinical history, weight, height, and drug history are recorded. At baseline and at the end of the study serum fasting glucose and HbA1C will be measured. Patients will consume supplement/placebo for 12 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having Type II diabetes diagnosed by gastroenterologist, >18 years old, Willing to participate  
Exclusion criteria: Pregnancy and lactation, Patients on insulin therapy, Having known kidney disease

##### Intervention groups

Patients will receive 1000 mg softgel containing 900 mg black seed and 100 mg cumin oil or placebo every 12 hours. Placebo softgel contain sunflower oil

##### Main outcome variables

serum fasting glucose and HbA1C

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140804018677N16**

Registration date: **2022-04-24, 1401/02/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-24, 1401/02/04**

Update count: **0**

##### Registration date

2022-04-24, 1401/02/04

##### Registrant information

###### Name

soodeh razeghi Jahromi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6634 8500

###### Email address

razeghi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-08-23, 1401/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the effect of Cumin (Cuminum Cyminum L) and black seed (Nigella sativa) on glycemic control

##### Public title

Assessing the effect of Cumin and black seed on glycemic control

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Having Type II diabetes diagnosed by gastroenterologist  
>18 years old Willing to participate

**Exclusion criteria:**

Pregnancy and lactation Patients on insulin therapy  
Having known kidney disease

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code (supplement and placebo) at the time of sampling. The following groups of people involved in the trial: participants, Research team including principle investigator, data collectors, and outcome assessors will be blind

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti medical university

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Approval date**

2022-02-27, 1400/12/08

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1400.1132

**Health conditions studied**

1

**Description of health condition studied**

Type 2 diabetes

**ICD-10 code**

E11.65

**ICD-10 code description**

Type 2 diabetes mellitus with hyperglycemia

**Primary outcomes**

1

**Description**

Fasting serum glucose level

**Timepoint**

Baseline and at the end of the study

**Method of measurement**

Blood test

2

**Description**

Serum HbA1C level

**Timepoint**

Serum HbA1C level

**Method of measurement**

Blood test

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: Consuming 1000 mg softgel containing 900 mg black seed and 100 mg cumin oil every 12 hours for 12 weeks

#### Category

Treatment - Other

### 2

#### Description

Control group: Consuming 1000 mg softgel containing sunflower oil, every 12 hours for 12 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Fayaz Bakhsh Hospital

##### Full name of responsible person

Soodeh Razeghi Jahromi

##### Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

##### City

Tehran

##### Province

Tehran

##### Postal code

1981619573

##### Phone

+98 21 2235 7483

##### Email

soodehrazeghi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1981619573

##### Phone

+98 21 2235 7483

##### Email

soodehrazeghi@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Soodeh Razghei Jahromi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

##### Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

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Tehran

##### Province

Tehran

##### Postal code

193954741

##### Phone

+98 21 2235 7483

##### Email

soodehrazeghi@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Soodeh Razghei Jahromi

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data would be available to public

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

To all

**Under which criteria data/document could be used**

No other criteria

**From where data/document is obtainable**

Email to soodehrazeghi@gmail.com

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

sending email to me

**Comments**