

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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,

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Phone

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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

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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

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

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Person responsible for scientific inquiries

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

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