Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim
Determinig 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 demografic information, cllinical 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 critaria: Having Type II diabetes diagnosed by gastroenterologist, >18 years old, Willing to participate
Exclusion critaria: 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
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Iran (Islamic Republic of)
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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 packets 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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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
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Other areas of specialty/work
Nutrition
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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
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