Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Cumin (Cuminum cyminum) soft capsule on glycemic markers, lipid profile, and leptin in prediabetic patients.

Protocol summary

Summary

This study aimed to assess the effect of cumin soft gel on glycemic markers, lipid profile, and leptin in prediabetic subjects. In this rendomized controlled-placebo trial, patients will be enrolled if they were prediabetic according to American Diabetic Association, and who do not have other metabolic problems or who do not use drugs with interaction with cumin. Àccording to previous studies, 25 subjects will be needed for each group but to avoid the loss, 32 subjects will be enrolled. After filling out the written consent form, patients were included in the study as 2 parallel groups. The intervention group will receive 75 mg cumin soft gel before the meal 3 times a day) while the placebo group will receive placebo (in the same shape and color). The intervention lunches for 10 weeks. Before and after the intervention, 10 cc blood will receive from each patient and biochemical assessments will perform. Glycemic markers (fasting blood sugar, glycosylated hemoglobin, insulin), lipid profile, and leptin will be measured for each patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111930962N1**
Registration date: **2017-02-19, 1395/12/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-19, 1395/12/01

Registrant information

Name

Tina Jafari

Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Cumin (Cuminum cyminum) soft capsule on glycemic markers, lipid profile, and leptin in prediabetic patients.

Public title

Effect of Cumin on prediabetic patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: FBS between 100-125mg/dl or 2 hours after GTT (75mg glucose) BS between 140-199 mgldl or HbA1C between 5.7-6.7; Patients without liver, renal, or endocrine disorders or malignancy; Patients who do not use any drugs with significant interaction with cumin like anti-depressant; Willing to participation and filling the written consent Exclusion criteria: not willing to participation; disobedience from the study protocol;

having special diets; any liver, renal, or endocrine disorders or malignancy during the intervention; consuming vitamin D, omega-3, selenium, or anti-depressant drugs; change in the drug history during the intervention 7- using insulin

Age
From **20 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord University of Medical Sciences

Street address
Shahrekord, University of Medical Sciences

City
Shahrekord

Postal code

Approval date
2016-10-22, 1395/08/01

Ethics committee reference number
IR.skums.rec.1395.223

Health conditions studied

1

Description of health condition studied
Pre diabetes

ICD-10 code
R73.0

ICD-10 code description
Abnormal glucose tolerance test

Primary outcomes

1

Description
FBS (glycemic index)

Timepoint
Before (day 0) and after intervention (after 10 weeks intervention)

Method of measurement
Valid biochemistry kits (Pars Azmoon)

2

Description
hbA1C (glycemic index)

Timepoint
Before (day 0) and after intervention (after 10 weeks intervention)

Method of measurement
Valid biochemistry kits (Pars Azmoon)

3

Description
Insulin (glycemic index)

Timepoint
Before (day 0) and after intervention (after 10 weeks intervention)

Method of measurement
Valid biochemistry kits (Pars Azmoon)

Secondary outcomes

1

Description
Lipid profile

Timepoint
Before and after intervention

Method of measurement
Valid biochemistry tests

2

Description
Serum leptin

Timepoint
Before and after intervention

Method of measurement
Elisa kit

Intervention groups

1

Description
The intervention group will receive75 mg cumin soft gel (25 mg TID). . The intervention period will lunched 10 weeks

Category
Placebo

2

Description
The control group will receive placebo (the same as cumin soft gel) before each meal for 10 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Treatment centers in Shahrekord
Full name of responsible person
Dr.Parviz Tahmasebi
Street address
Bahonar ST., Shahrekord, Iran
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice President of Research, Shahrekord University of Medical Sciences
Full name of responsible person
Dr. Kamal Solati, Research assistant
Street address
Department part 2, Vice President of Research, University of Medical Sciences, Ayat allah Kashani St, Shahrekord, Iran
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice President of Research, Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty