

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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 randomized 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. According 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

Country

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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 mg/dl 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 receive 75 mg cumin soft gel (25 mg TID). . The intervention period will last 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

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Tina Jafari

Position

Nutritionist, Assistant professor

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty