Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Cuminum Cyminum extract on glycemic indexes, serum hsCRP, TNF-α, lipid profile and anthropometric indexes in type II diabetic patients

Protocol summary

Summary

Introduction: Type II diabetes is a kind of disorder in the metabolism of carbohydrate. In the recent years, the green cumin has been identified as an herbal drug in treatment of the type II diabetes in the studies on the lab animals. The aim of this study is evaluation of the effect of 50 and 100 mg doses of the extract of the Cuminum Cyminum on the glycemic profile, lipid profile, inflammatory indicators and anthropometric indexes in the human samples with type II diabetes. Methods: The present study is a parallel single-blind clinical trial. After selecting the subjects based on the inclusion criteria, they will be divided to 3 groups randomly: 1- the group who will use the extract of the Cuminum Cyminum (100 mg/day), 2- the group who will use the extract of the Cuminum Cyminum (50 mg/day), 3- the control group (placebo). First, a blood sample will be drawn and the FBS, sensitivity to insulin with index of HOMA-IR, HgA1c, inflammatory indicators including hsCRP and TNF-α, lipid indicators including total cholesterol, LDL, HDL, TG and VLDL, anthropometric indexes including height, weight, waist circumference, hip circumference, and the thickness of the skin fold will be measured. Then, supplementation will be continued for 8 weeks. After the end of supplementation, again the blood sample will be drawn and the above-mentioned indicators will be measured. Then all this information will be entered into the SPSS software and the effect of supplementation will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101113678N9**
Registration date: **2016-03-16, 1394/12/26**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-03-16, 1394/12/26

Registrant information

Name
Saeed Ghavamzadeh
Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Urmia University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cuminum Cyminum extract on glycemic indexes, serum hsCRP, TNF-α, lipid profile and anthropometric indexes in type II diabetic patients

Public title

The effect of cumin extract on type 2 diabetes

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria FBS higher than 126 mg/dL and lower than 200 mg/dL; controlled statues of lipid and sugar of the blood; single medication schedule in the samples; lack of insulin therapy; do not to use of tobacco and alcohol; absence of the chronic disease; lack of pregnancy and lactation; lack of menopause; and lack of hormone therapy. Exclusion criteria: Sensitivity to the extract of the green cumin; conception during study; variation in the dose of the medications during study; and developing to the diseases during study
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia University of Medical Science
Street address
Nazlu pardis, Urmia
City
Urmia
Postal code
Approval date
2015-09-09, 1394/06/18
Ethics committee reference number
IR.UMSU.Rec.1394.186

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes
ICD-10 code
E-11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Body Mass Index
Timepoint
Before and after 8 weeks intervention
Method of measurement
Formula

2

Description
Body fat percent
Timepoint
Before and after 8 weeks intervention
Method of measurement
Caliper

3

Description
Non fat tissue percentage
Timepoint
Before and after 8 weeks intervention
Method of measurement
Caliper

4

Description
Waist circumference
Timepoint
Before and after 8 weeks intervention
Method of measurement
Meter

5

Description
High sensitive C Reactive Protein
Timepoint
Before and after 8 weeks intervention
Method of measurement
ELISA

6

Description
Total Cholesterol
Timepoint
Before and after 8 weeks intervention
Method of measurement
Enzymatic

7

Description
Low Density Lipoprotein
Timepoint
Before and after 8 weeks intervention
Method of measurement
Enzymatic

8

Description
High Density Lipoprotein
Timepoint
Before and 8 weeks after intervention
Method of measurement
Enzymatic

9

Description
Very Low Density Lipoprotein
Timepoint
Before and after 8 weeks intervention
Method of measurement
Enzymatic

10

Description
Fast Blood Sugar
Timepoint
Before and after 8 weeks intervention
Method of measurement
Enzymatic

11

Description
Insulin
Timepoint
Before and after 8 weeks intervention
Method of measurement
ELISA

12

Description
Hemoglobin A1c
Timepoint
Before and after 8 weeks intervention
Method of measurement
Colorimetry

13

Description
Insulin resistance
Timepoint
Before and after 8 weeks intervention
Method of measurement
Formula

14

Description
Tumor Necrosis Factor
Timepoint
Before and after 8 weeks intervention
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Cuminum Cyminum extract (Barij Essence company) , soft gel 25 milligrams , four times daily for 8 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: Cuminum Cyminum extract(Barij Essence company) , soft gel 25 milligrams , twice daily for 8 weeks
Category
Treatment - Drugs

3

Description
Intervention group 3: placebo (oral paraffin oil) , soft gel 25 milligrams(Zahravi company) , twice daily for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Number 2 clinic of Imam Khomeini Hospital
Full name of responsible person
Street address
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Mr. Nazari

Street address
Resalat Ave, Urmia University of Medical Science
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urmia 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Dr. Saeed Ghavamzadeh
Position
PhD in Nutrition Science
Other areas of specialty/work
Street address
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Postal code
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Person responsible for updating data

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Sahar Jafari Karegar
Position
Master of Science
Other areas of specialty/work
Street address
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Fax
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Web page address

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