

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

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Name of organization / entity

Urmia University of Medical Sciences

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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 statuses 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

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Fax**Email****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*