Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Cuminum cyminum L. supplementation on components, inflammatory and oxidative stress indices in patients with metabolic syndrome.

Protocol summary

Summary

The objective of this randomized double-blind placebo controlled trial is to assess the effect of Cuminum cyminum L. supplementation on components, inflammatory and oxidative stress indices in patients with metabolic syndrome. Subjects will be recruited to the study, according to inclusion criteria and exclusion criteria.Subjects including 44 individuals from both sexes will be randomly divided into two intervention and control groups.Subjects in intervention and control group will receive 75 mg three times a day of cumin or placebo respectively for 8 weeks. The assignment of groups will cover from the investigators and the subjects. Fasting blood samples, blood pressure and anthropometric measurements, 3 dietary records for each person will be performed at the beginning and end of the study. The levels of markers of inflammatory and oxidative, blood sugar, lipid profile and insulin in the fasting blood samples will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701193140N20**
Registration date: **2017-03-29, 1396/01/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-29, 1396/01/09

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Cuminum cyminum L. supplementation on components, inflammatory and oxidative stress indices in patients with metabolic syndrome.

Public title

The effect of Cumin pearl on treatment of metabolic syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate; age 18-60 years; affected by metabolic syndrome with three out of five criteria: waist circumference>91 cm in women and

>89 cm for men; serum triglyceride≥150 mg/dL; fasting serum glucose≥100mg/dL; serum HDL-C<40 mg/dL in men and <50 mg/dl in women; systolic blood pressure≥130mmhg and/or diastolic blood pressure≥ 85mmhg. Exclusion criteria: pregnancy or lactation; usage of insulin; renal or liver failure; thyroid disorder; following a specific diet; alcohol intake; smoking; being menopause; usage of nutritional supplement in the past 3 month of the study; taking of corticosteroids or immunosuppressive drugs ....

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

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
Ethics committee of Tabriz University of Medical Sciences

Street address
No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City
Tabriz

Postal code

Approval date
2017-01-23, 1395/11/04

Ethics committee reference number
IR.TBZMED.REC.1395.1168

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome

ICD-10 code
E88.9

ICD-10 code description
metabolic disorders not specified

Primary outcomes

1

Description
Anthropometric idices

Timepoint
Baseline and end of study

Method of measurement
Stadiometer, Scale, Tape

2

Description
Lipid profile

Timepoint
Baseline and end of study

Method of measurement
Biochemical Analysis

Secondary outcomes

1

Description
Insulin

Timepoint
Baseline and end of study

Method of measurement
ELISA

2

Description
Energy intake

Timepoint
Baseline and end of study

Method of measurement
Three day dietary record questionnare

3

Description
Macronutrient

Timepoint
Baseline and end of study

Method of measurement
Three day dietary record questionnare

4

Description
Micronutrient

Timepoint
Baseline and end of study

Method of measurement
Three day dietary record questionnare

5

Description
Hemoglobin A1c
Timepoint
Baseline and end of study
Method of measurement
Spectrophotometry

6

Description
Fasting Blood Sugar
Timepoint
Baseline and end of study
Method of measurement
Spectrophotometry

7

Description
Insulin resistance
Timepoint
Baseline and end of study
Method of measurement
Formula

8

Description
MDA
Timepoint
Baseline and end of study
Method of measurement
Spectrophotometry

9

Description
Total anti oxidant
Timepoint
Baseline and end of study
Method of measurement
Spectrophotometry

10

Description
Catalase
Timepoint
Baseline and end of study
Method of measurement
Spectrophotometry

11

Description
Superoxide dismutase
Timepoint
Baseline and end of study
Method of measurement
Spectrophotometry

12

Description
High sensitive C-Reactive Protein
Timepoint
Baseline and end of study
Method of measurement
Spectrophotometry

13

Description
Tumor Necrosis Factor
Timepoint
Baseline and end of study
Method of measurement
ELISA

14

Description
Systolic and diastolic blood pressure
Timepoint
Baseline and end of study
Method of measurement
Digital monometer

Intervention groups

1

Description
Intervention group: Cumin essential oil capsule (75 mg), 3 times a day for 8 weeks
Category
Prevention

2

Description
Contol group: Placebo capsule (75mg), 3 times a day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Salahadin Ayubi Hospital, Kurdistan University of Medical Science
Full name of responsible person
Dr. Rashed Mahdavi
Street address
Salahadin Ayubi Hospital, Salahadin ayubi Street, Baneh
City
Baneh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Rashidi

Street address
No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research, Tabriz 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
Faculty of Nutrition and Food Science, Tabriz University of Medical Sceinces

Full name of responsible person
Ashti Morovati

Position
Master Candidate of Nutrition Science

Other areas of specialty/work

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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*