Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of cuminum cyminum on metabolic syndrome indicators in reproductive age women

Protocol summary

Study aim
Effect of cuminum cyminuim on metabolic syndrome indices in women of reproductive age referring to comprehensive health services centers of Rafsanjan, 1397

Design
Clinical trial with control group،Triple Blind, Simple Randomization

Settings and conduct
A triple controlled clinical trial with placebo.In this trial, the drug and placebo packs are coded by the pharmacist.As a result, patient, researcher, and data analyst are unaware of the nature of each individual case.Samples will be selected among women of reproductive age (aged 15-45) who are referred to the health centers of Rafsanjan.Then, based on entry criteria and simple random allocation, the two groups will receive 500 mg of cumin every 12 hours and placebo.

Participants/Inclusion and exclusion criteria
Inclusion measures: Women aged 18-45 Unwillingness to be pregnant Lack of chronic disease (cardiovascular disease, history of myocardial infarction, cerebrovascular accident, kidney and liver disease, cancer, mental illness) Not having weight loss regimens Not pregnancy Not smoking and alcohol Non-use of drugs Not taking warfarin and heparin Exclusion measures: Sensitization to drug No drug intake for two consecutive days Pregnancy during the study period Unwillingness to continue cooperation Having one of the diseases listed during the study period Participate in sports classes during the study

Intervention groups
Intervention group:The intervention group is asked to take one capsule of 500 mg cuminum cyminium every 12 hours with a glass of water after a meal. control group:The control group is asked to take a placebo capsule every 12 hours with a glass of water after a meal.

Main outcome variables
Mean concentration of fasting glucose Triglyceride High Density Lipoprotein Blood Pressure Waist size

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160308026971N7**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **retrospective**

Last update: **2020-02-08, 1398/11/19**
Update count: **0**

Registration date
2020-02-08, 1398/11/19

Registrant information

Name
Marzeyeh Loripoor

Name of organization / entity
Rafsanjan University Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-20, 1397/10/30

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
2019-01-20, 1397/10/30

Actual recruitment end date

2019-09-21, 1398/06/30

Trial completion date

2019-09-21, 1398/06/30

Scientific title

The effect of cuminum cyminum on metabolic syndrome indicators in reproductive age women

Public title

Effect of Cuminum cyminum on Metabolic Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 15-45 Use of contraceptive methods Not pregnant Having three of the five criteria for metabolic syndrome

Exclusion criteria:

Drug sensitivity No drug intake for two consecutive days Unwillingness to continue cooperation Participate in sports classes chronic disease Weight loss diets Alcoholism, tobacco and drugs abuse Use of warfarin and heparin

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization using Random Number Table

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this trial, drug and placebo packs are coded by the pharmacist.As a result, the patient, the researcher and the data analyst are unaware of the nature of each packet

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Science

Street address

Central department of Rafsanjan University Medical Science،immam Ali Street

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Rafsanjan

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Kerman

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7717932777

Approval date

2019-01-09, 1397/10/19

Ethics committee reference number

IR.RUMS.REC.1397.181

Health conditions studied

1

Description of health condition studied

Metabolic syndrom

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean concentration of fasting plasma glucose ، Triglyceride ،High Density Lipoprotein، Blood Pressure،Waist

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

The mean fasting plasma glucose concentration is based on the laboratory's response.Triglyceride is based on the laboratory's response. High Density Lipoprotein is a based on the laboratory's response.Hypertension is using a blood pressure monitor,The waist is measured using non-elastic bandwidth meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A 500-mg capsule made from cumin every 12 hours will be taken with a glass of water after eating for 8 weeks, whicht was made by the Iranian

faculty of Medical Sciences College of Kerman Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: A placebo capsule containing "starch" that takes all the same appearance as the cumin capsule, will take one tablet every 8 hours for 12 hours.whicht was made by the Iranian faculty of Medical Sciences College of Kerman Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز بهداشتی درمانی شماره 1

Full name of responsible person

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Recruitment center

Name of recruitment center

مرکز بهداشتی درمانی شماره 2

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Recruitment center

Name of recruitment center

مرکز بهداشتی درمانی شماره 3

Full name of responsible person

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مرکزبهداشتی درمانی شماره3،روبه روی بانک مرکزی،خیابان شریعتی غربی

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Recruitment center

Name of recruitment center

مرکز بهداشتی درمانی شماره 4

Full name of responsible person

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5

Recruitment center

Name of recruitment center

Healt center No.5

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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Web page address
http://vcrt.rums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available