

# 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 cyminum 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 cyminum 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3428 4950

##### Email address

m.loripoor@rums.ac.ir

##### 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

##### **City**

Rafsanjan

##### **Province**

Kerman

##### **Postal code**

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, which 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. which 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**

شیرین محمودی

**Street address**

Healt Center No.1, Imam khomeini Ave. Qods Sq

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717653548

**Phone**

+98 34 3428 2075

**Email**

ava.man623@yahoo.com

**2**

**Recruitment center**

**Name of recruitment center**

مرکز بهداشتی درمانی شماره 2

**Full name of responsible person**

شیرین محمودی

**Street address**

مرکز بهداشتی درمانی شماره 2، کوچه 41، خیابان 15 خرداد

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

771433579

**Phone**

+98 34 3423 0887

**Email**

amiirsh@gmail.com

**3**

**Recruitment center**

**Name of recruitment center**

مرکز بهداشتی درمانی شماره 3

**Full name of responsible person**

شیرین محمودی

**Street address**

مرکز بهداشتی درمانی شماره 3، روبه روی بانک مرکزی، خیابان شریعتی غربی

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7713654887

**Phone**

+98 34 3425 9164

**Email**

sangielah@yahoo.com

**4**

**Recruitment center**

**Name of recruitment center**

مرکز بهداشتی درمانی شماره 4

**Full name of responsible person**

شیرین محمودی

**Street address**

Healt center No.4, Amir Kabir St. in front the childrins park

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718663316

**Phone**

+98 34 3432 5911

**Email**

alipourzohre@yahoo.com

**5**

**Recruitment center**

**Name of recruitment center**

Healt center No.5

**Full name of responsible person**

Shirin Mahmoodi

**Street address**

Healt center No.5, Kargar St

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7716676788

**Phone**

+98 34 3425 3035

**Email**

marzeyeloriipoor@yahoo.com

**6**

**Recruitment center**

**Name of recruitment center**

Healt center No.6

**Full name of responsible person**

Shirin Mahmoodi  
**Street address**  
Healt center No.6.Mostafa Khomeini Street  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7714645553  
**Phone**  
+98 34 3422 3090  
**Email**  
shojaeibehnazz@gmail.com

## 7

### Recruitment center

**Name of recruitment center**  
Healt center No.7  
**Full name of responsible person**  
shirin Mahmoodi  
**Street address**  
Healt center No.7,Shahid Shafiei,Hojjat  
Bolvar,Shahrak Valfajr  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7717837899  
**Phone**  
+98 34 3435 3427  
**Email**  
mohebbimama@yahoo.com

## 8

### Recruitment center

**Name of recruitment center**  
Healt center no.8  
**Full name of responsible person**  
Shirin Mahmoodi  
**Street address**  
Healt center no.8.near Gaz station.Azadi Bolvar  
**City**  
rafsanjan  
**Province**  
Kerman  
**Postal code**  
7717964849  
**Phone**  
+98 34 3428 2075  
**Email**  
pormohammadali@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Rafsanjan University of Medical Sciences

#### Full name of responsible person

Dr.Ali Shamsizadeh

#### Street address

Imam ali Bolvar.Research &Technology.central Office  
of Rafsanjan university of Medical sciences

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7717933777

#### Phone

+98 34 3428 0097

#### Fax

+98 34 3428 0097

#### Email

alishamsy@gmail.com

#### 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

Rafsanjan University of Medical Sciences

#### Full name of responsible person

Marzeyeh Loripoor

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Midwifery

#### Street address

Faculty of Nursing and Midwifery.Nursing Street

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7718796755

#### Phone

+98 34 3428 5900

#### Fax

+98 34 3425 8497

**Email**

marzeyehloripoor@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

marzeyeh Loripoor

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

faculty of Nursing and midwifery.Nursing street

**City**

rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

marzeyehloripoor@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Marzeyeh Loripoor

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

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**City**

rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

marzeyehloripoor@yahoo.com

**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