

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### effect of cinnamon powder capsule on some of lipid and blood sugar profile in overweight or obese women with polycystic ovary syndrome

#### Protocol summary

##### Summary

Objective: To determine the effect of cinnamon capsules on some lipid and blood sugar in overweight or obese women with polycystic ovary syndrome in women referred to clinics affiliated to Shiraz University of Medical Sciences in 2016 this study is Controlled, single-blind randomized clinical trial Study population: All women of childbearing age (18-40 years) women with polycystic ovary who referred to clinic of Shiraz University of Medical Sciences The main inclusion criteria:want to participate in study-Study, diagnosis of polycystic ovary syndrome by a gynecologist- having a body mass index of 25 or more-the age range between18-40 do not have any previous allergy to cinnamon the main exclusion criteria do not want to continue the study-The incidence of any adverse allergic to cinnamon consumption-pregnancy sample size:62 people intervention:They were randomly divided into control and experimental groups and use three grams of cinnamon powder or cellulose as placebo capsules daily for two months.Before and after the intervention blood sample will taken to assess lipid and blood sugar profiles Consequences:Is expected to follow the consumption of cinnamon lipid and blood sugar profile levels reduced or adjusted index

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015122025618N1**  
Registration date: **2016-01-25, 1394/11/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-01-25, 1394/11/05

#### Registrant information

##### Name

Mehrnoosh Hatamzadeh

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3831 1946

##### Email address

stud2301111741@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Shiraz University of Medical Sciences

#### Expected recruitment start date

2016-01-03, 1394/10/13

#### Expected recruitment end date

2016-07-03, 1395/04/13

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

effect of cinnamon powder capsule on some of lipid and blood sugar profile in overweight or obese women with polycystic ovary syndrome

#### Public title

the effect of cinnamon on lipid and blood sugar in polycystic ovary syndrome

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

inclusion criteria:people who want to participate in study and full fill the informed consent form;Before choosing the sample, polycystic ovarian syndrome diagnosed by

the gynecologist based on Rotterdam criteria;people have body mass index 25 or more;people age range is between18-40;have not Previous history of allergy to cinnamon consumption;do not have hypertension;do not have diabetes mellitus;do not have cardio vascular disease;do not have hepatic disease;do not have renal disease;do not have Cerebrovascular disease;do not have Seizure disorders;do not have Increased levels of the prolactin or other endocrine disorders;do not have Hypothyroidism or hyperthyroidism;do not have adrenal disorders;do not have cancer;do not have infertility;do not have history of alcohol use or smoking;do not use hormone therapy during three months prior to study;do not use hormonal contraception during three months prior to study;do not use insulin sensitizing drug during three months prior to study;do not be during pregnancy or breast feeding period; exclusion criteria do not want to continue the study;In case of any allergic symptoms after taking cinnamon;cinnamon consumption cut and will be excluded;In the event of pregnancy;cinnamon consumption cut and will be excluded;In case of loss of any inclusion criteria drug use will be cut and people excluded from the study

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **62**

**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**

Shiraz University of Medical Sciences

**Street address**

Central Building of Shiraz University of Medical Sciences,Zand Street, Shiraz

**City**

Shiraz

**Postal code**

713451978

**Approval date**

2015-12-16, 1394/09/25

**Ethics committee reference number**

ir.sums.rec.1394.155

**Health conditions studied****1****Description of health condition studied**

polycystic ovary syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Sclerocystic ovary syndromeStein-Leventhal syndrome

**Primary outcomes****1****Description**

body mass index

**Timepoint**

before intervention and after intervention

**Method of measurement**

Kilograms per height in square meters by the formula

**2****Description**

weight

**Timepoint**

before study and after study

**Method of measurement**

kilogram by using scale

**3****Description**

height

**Timepoint**

before intervention and after intervention

**Method of measurement**

centimetre by using metre

**4****Description**

fasting glucose

**Timepoint**

before intervention and after intervention

**Method of measurement**

Milligrams per deciliter by use blood samples and laboratory testing

**5****Description**

fasting insulin

**Timepoint**

before intervention and after intervention

**Method of measurement**

Micro units per milliliters of blood samples and laboratory testing

**6****Description**

Insulin resistance

**Timepoint**

before intervention and after intervention

**Method of measurement**

by using formula

**7****Description**

Oral glucose tolerance test

**Timepoint**

before intervention and after intervention

**Method of measurement**

Milligrams per deciliter by using blood sample and laboratory testing

**8****Description**

Cholesterol

**Timepoint**

before and after intervention

**Method of measurement**

Milligrams per deciliter by using blood samples and laboratory testing

**9****Description**

low density lipoprotein

**Timepoint**

before and after intervention

**Method of measurement**

Milligrams per deciliter by using blood samples and laboratory testing

**10****Description**

high density lipoprotein

**Timepoint**

before and after intervention

**Method of measurement**

Milligrams per deciliter by using blood samples and laboratory testing

**11****Description**

triglyceride

**Timepoint**

before and after intervention

**Method of measurement**

Milligrams per deciliter by using blood samples and laboratory testing

**Secondary outcomes****1****Description**

abdominal pain

**Timepoint**

before and during and after intervention

**Method of measurement**

Periodic follow-up by telephone call

**2****Description**

itching

**Timepoint**

before and during and after intervention

**Method of measurement**

Periodic follow-up by telephone call

**3****Description**

headache

**Timepoint**

before and during and after intervention

**Method of measurement**

Periodic follow-up by telephone call

**4****Description**

hives

**Timepoint**

before and during and after intervention

**Method of measurement**

Periodic follow-up by telephone call

**5****Description**

asthma

**Timepoint**

before and during and after intervention

**Method of measurement**

Periodic follow-up by telephone call

**6****Description**

Respiratory allergies

**Timepoint**

before and during and after intervention

**Method of measurement**

Periodic follow-up by telephone call

**7****Description**

diarrhea

**Timepoint**

before and during and after intervention

**Method of measurement**

Periodic follow-up by telephone call

## 8

### Description

nausea

### Timepoint

before and during and after intervention

### Method of measurement

Periodic follow-up by telephone call

## 9

### Description

heartburn

### Timepoint

before and during and after intervention

### Method of measurement

Periodic follow-up by telephone call

## Intervention groups

### 1

#### Description

the intervention group use cinnamon powder capsules three times a day and each time two 500- milligram capsules(a total of 3 grams per day) orally for two months

#### Category

Treatment - Drugs

### 2

#### Description

control group use cellulose capsule three times a day and each time two 500-miligram capsules (a total of three grams per day) orally for two months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gynecology Clinic of Faghihi Hospital

##### Full name of responsible person

Doctor Fatemehsadat Najib(Gynecologist-Assistant professor)

##### Street address

Faghihi Hospital,Zand street,Shiraz

##### City

Shiraz

### 2

#### Recruitment center

##### Name of recruitment center

Motahari Clinic(Gynecology Clinic)

##### Full name of responsible person

Doctor Fatemehsadat Najib(Gynecologist-Assistant professor)

##### Street address

Motahari Clinic,Namazi Square,Shiraz

##### City

Shiraz

### 3

#### Recruitment center

##### Name of recruitment center

Clinic of Zeinab Hospital

##### Full name of responsible person

Doctor Fatemehsadat Najib(Gynecologist-Assistant professor)

##### Street address

Zeinab Hospital,Defamoghaddas Square,Shiraz

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

shiraz universirty of medical sciences

##### Full name of responsible person

Vice President of Research and Technology

##### Street address

shiraz-zand street-Central Building of shiraz University of Medical Sciences

##### City

shiraz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

shiraz universirty 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

Fatemeh School of Nursing and Midwifery, Shiraz University of Medical Sciences

##### Full name of responsible person

Zeinab Moshfeghy

##### Position

Master of Midwifery

**Other areas of specialty/work**

**Street address**

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**Full name of responsible person**

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Midwifery Students

**Other areas of specialty/work**

**Street address**

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**Email**

stud2301111741@sums.ac.irmehrnoosh.hatamzadeh  
@yahoo.com

**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*