

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of cinnamon and ginger compared with metformin on anthropometric data, on Blood Glucose, Lipid and sexual hormones in women with polycystic ovary syndrome

#### Protocol summary

##### Study aim

The effect of cinnamon and ginger compared with metformin on anthropometric data, Blood Glucose, Lipid and sexual hormones in women with polycystic ovary syndrome

##### Design

In this study, 100 patients with polycystic ovarian syndrome who were admitted to Motahari clinic of Shiraz were selected. The participants were randomly divided into four intervention and control groups and each participant was given a code Allocated

##### Settings and conduct

This study was done on the treatment of polycystic ovaries in Motahhari clinic of Shiraz in the form of double-blind clinical trial. blinding was performed by producing similar in shape capsules and in different colors

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Age 40-20 years; Willingness to participate in the study; Poly cystic ovary syndrome diagnosis by a specialist according to Rotterdam criteria  
Exclusion criteria Diabetes mellitus; Hypersensitivity, Hyperprolactinemia, Thyroid problems, seizure, cardiovascular disease and cerebrovascular disease  
Pregnancy; lactation; Infertility treatment; using Blood glucose-lowering drugs or Blood glucose lowering drugs; using Insulin secretagogues drugs; using Contraceptives drugs; using Beta-blockers; cinnamon; ginger allergy; Need for OCP treatment

##### Intervention groups

Control group: Consume capsules containing 500 mg of rice flour as a placebo three times a day; Intervention group 1: Consume capsules containing 500 mg of ginger three times a day; Intervention group 2: Consume capsules containing 500 mg of cinnamon three times a day; Intervention group 3: Consume capsules containing 500 mg metformin three times a day

#### Main outcome variables

Weight, Waist circumference, Hip circumference, Fasting blood glucose, Insulin, Cholesterol, Triglyceride, High density lipoprotein, Low density lipoprotein, Luteinizing hormone, Follicular stimulatory hormone, Testosterone, dihydroepidestrone, Sexual Hormone binding globulin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171227038105N1**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **retrospective**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

##### Registration date

2018-01-30, 1396/11/10

##### Registrant information

##### Name

marsa dastgheib parsa

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3725 1001

##### Email address

mdastgheib@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2017-10-23, 1396/08/01  
**Actual recruitment start date**  
2017-08-01, 1396/05/10  
**Actual recruitment end date**  
2017-11-22, 1396/09/01  
**Trial completion date**  
empty

#### Scientific title

The effect of cinnamon and ginger compared with metformin on anthropometric data, on Blood Glucose, Lipid and sexual hormones in women with polycystic ovary syndrome

#### Public title

Cinnamon and Ginger and Metformin for the treatment of polycystic ovary syndrome

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 40-20 years Willingness to participate in the study Polycystic ovary syndrome diagnosis by a specialist according to Rotterdam criteria

##### Exclusion criteria:

Diabetes mellitus Pregnancy Infertility treatment using Blood glucose-lowering drugs or Blood glucose lowering drugs cinnamon allergy Need for OCP treatment ginger allergy using Beta-blockers using Contraceptives Hypersensitivity Hyperprolactinemia Thyroid problems seizure cardiovascular disease cerebrovascular disease lactation using Insulin secretagogues

#### Age

From **20 years** old to **40 years** old

#### Gender

Female

#### Phase

2

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **100**

Actual sample size reached: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Block randomization

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The study was performed in a double-blind manner. The participant, the researcher, the outcome evaluator, the data analyzer were not informed of intervention performed in the form of a random, and only the clinical caregiver knew the type of treatment

#### 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

The headquarters of Shiraz University of Medical Sciences, Opposite of Palestine Street, Zand Street, Shiraz, Iran

##### City

shiraz

##### Province

Fars

##### Postal code

14336 - 71348

#### Approval date

2017-06-11, 1396/03/21

#### Ethics committee reference number

IR.SUMS.REC.1396.41

#### Health conditions studied

##### 1

#### Description of health condition studied

Polycystic Ovary Syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovary syndrome

#### Primary outcomes

##### 1

#### Description

weight

#### Timepoint

Before the experiment, eight weeks after intervention

#### Method of measurement

Balance

##### 2

#### Description

Waist circumference

#### Timepoint

Before the experiment, eight weeks after intervention

#### Method of measurement

Tape

### 3

**Description**

Hip circumference

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Tape

### 4

**Description**

FBS

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 5

**Description**

Insulin

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 6

**Description**

Cholesterol

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 7

**Description**

TG

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 8

**Description**

HDL

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 9

**Description**

LDL

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 10

**Description**

LH

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 11

**Description**

FSH

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 12

**Description**

Testosterone

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 13

**Description**

dehydroepiandrosterone

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

### 14

**Description**

SHBG

**Timepoint**

Before the experiment, eight weeks after intervention

**Method of measurement**

Standard enzymatic method

## Secondary outcomes

### 1

**Description**

BMI

**Timepoint**

Before the intervention and one day after the end of the intervention

**Method of measurement**

weight divide into height<sup>2</sup>

## Intervention groups

### 1

**Description**

First intervention group: Ginger - capsule 500 mg - 3

times a day - 8 weeks

**Category**

Treatment - Other

**2**

**Description**

Second intervention group: Ginger - 500 mg capsule - 3 times a day - 8 weeks

**Category**

Treatment - Other

**3**

**Description**

Third intervention group: metformin - 500 mg capsule - 3 times a day - 8 weeks

**Category**

Treatment - Drugs

**4**

**Description**

Control group: Rice flour - 500 mg capsule - 3 times a day - 8 weeks

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Motahari Hospital

**Full name of responsible person**

Sedighe Amooii

**Street address**

Namazi Square

**City**

Shiraz

**Province**

Fars

**Postal code**

14336 - 71348

**Phone**

+98 71 3612 1000

**Email**

sedighehamooee@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Syyed Basir Hashmi

**Street address**

Seventh Floor, Office of Research and Technology,  
Central Building of Shiraz University of Medical

Sciences, Opposite of Palestine Street, Zand Street,  
Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

14336 - 71348

**Phone**

+98 71 3230 5410

**Email**

mdastgheib@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Marsa Dastgheib Parsa

**Position**

Master of Science in Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Department of Nutrition and Food Science, Facing the  
Power Club, Razi Blvd, Shiraz, Iran

**City**

shiraz

**Province**

Fars

**Postal code**

7153675541

**Phone**

+98 71 3725 1001

**Email**

mdastgheib@sums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Siyavash Babajafari

**Position**

MD PhD, nutritional sci

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Nutrition

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**Email**

jafaris@sums.ac.ir

**Phone**

+98 71 3725 1001

**Email**

mdastgheib@sums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

After the study, information on the main and effective implications of interactions will be shared

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Data will be available to researchers working in academic and scientific institutions and industry professionals.

**Under which criteria data/document could be used**

The use of data will be allowed in the form of the source and the main author in the papers

**From where data/document is obtainable**

Through address: Shiraz - Faculty of Nutrition and Food Sciences phone number: 00989367560707 email: mdastgheib@sums.ac.ir

**What processes are involved for a request to access data/document**

After sending an email or referring to the address entered or by telephone, the information will be received by the applicant within a month.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Marsa Dastgheib Parsa

**Position**

Master of Science in Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Department of Nutrition and Food Science, Facing the Power Club, Razi Blvd, Shiraz, Iran

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**Postal code**

7153675541