

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 parsia

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 useing 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 useing 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 analyzerwere not informrd 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 height²

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. Syied 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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jafaris@sums.ac.ir

Phone

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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

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