Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 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 useing Blood glucose-lowering drugs or Blood glucose lowering drugs cinnamon allergy Need for OCP treatment ginger allergy useing Beta-blockers useing 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 devide 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

Šedighe Amooii

Street address

Namazi Square

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Shiraz

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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

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Seventh Floor, Office of Research and Technology, Central Builing of Shiraz University of Medical Sciences, Opposite of Palestine Street, Zand Street, Shiraz, Iran

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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

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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
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Medical doctor
Other areas of specialty/work
Nutrition
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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
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City
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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