Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of ginger powder supplementation on biochemical, hormonal, and inflammatory factors, and serum oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim
Determine the effects of ginger powder supplementation on biochemical, hormonal, and inflammatory factors, and serum oxidative stress in women with polycystic ovary syndrome

Design
This study is a double-blind clinical trial study with a control group and parallel groups, randomized using random assignment software (RAS) on 48 patients.

Settings and conduct
This study is a double-blind clinical trial study that will be conducted on patients with polycystic ovary syndrome referring to Ahvaz endocrinology office and clinic for 12 weeks and among them 48 people based on the inclusion and exclusion criteria of the study randomly They are divided into 2 intervention and control groups. Participants and researchers are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age above 18 years BMI above 18.5 Diagnosis and confirmation of polycystic ovary syndrome by an endocrinologist and metabolism specialist based on the Rotterdam criteria Exclusion criteria: Pregnancy Lactation Menopause Having other causes of hyperandrogenism such as congenital adrenal hyperplasia, Cushing's syndrome, ovarian or adrenal tumor Taking ginger supplements in the last three months

Intervention groups
The subjects of the intervention group received 2 capsules of 1 gram of ginger daily and the subjects of the control group received 2 placebos (starch content) daily, which are completely similar to ginger capsules in terms of appearance.

Main outcome variables
FBS; HbA1c; Ins; HOMA-IR; QUICKI; TC; TG; LDL-C; HDL-C; AIP; IL6; MDA; TAC; Leptin; Testosterone; SHBG; FAI; AMH; Hirsutism; Alopecia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221205056719N1**
Registration date: **2023-01-15, 1401/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-15, 1401/10/25**
Update count: **0**

Registration date
2023-01-15, 1401/10/25

Registrant information

Name
Zeinab Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3293 3116

Email address
heidari.z@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-10, 1401/10/20

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of ginger powder supplementation on biochemical, hormonal, and inflammatory factors, and serum oxidative stress in women with polycystic ovary syndrome

Public title
Ginger in PCOS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years BMI above 18.5 Diagnosis and confirmation of polycystic ovary syndrome by an endocrinologist and metabolism specialist based on the Rotterdam criteria Willingness to cooperate
Exclusion criteria:
Unwillingness to participate in the study Pregnancy Lactation Menopause Having other causes of hyperandrogenism such as congenital adrenal hyperplasia, Cushing's syndrome, ovarian or adrenal tumor Having any type of disease that affects hormonal parameters, such as hypoglycemia, diabetes, hyperprolactinemia, hyperparathyroidism, thyroid disorders, hypertension, anemia, allergies, asthma, cardiovascular, kidney, liver, lung, and cancer. Taking ginger supplements in the last three months Anticoagulant, diabetes and blood pressure medications (due to interference with ginger) during the study Following special diets
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the inclusion and exclusion criteria, people are randomly divided into 2 intervention groups and control groups by assigning three-digit codes by random assignment software (RAS). Allocation concealment will be used for concealment. This work is done using opaque envelopes sealed with a random sequence (Sequentially numbered, sealed, opaque envelopes). In this method, each of the random sequences created is recorded on a card and the cards will be placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the envelopes is glued and they are placed in a box. At the time of the registration of the participants, based on the order of entry of the eligible participants to the study, the envelopes will be opened in order and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Ginger capsules and placebo are distributed in containers that are identical in appearance and coded by a person other than the investigator. None of the participants and the investigator will know about the group in which the people are located, and the coding will be done by someone other than the researcher. Necessary explanations are provided for eligible people to participate in the research and informed consent is obtained from them.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapour University of Medical Sciences
Street address
Golestan highway, Jundishapour university of medical sciences
City
Ahvaz
Province
Khouzestan
Postal code
6194994986
Approval date
2022-12-04, 1401/09/13
Ethics committee reference number
IR.AJUMS.REC.1401.417

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Fasting blood sugar
Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

2

Description

Glycosylated hemoglobin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

3

Description

Serum insulin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

4

Description

Triglycerides

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

5

Description

Total cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

6

Description

High density lipoprotein cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

7

Description

Interleukin 6

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

8

Description

Total antioxidant capacity

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

9

Description

Malondialdehyde

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

10

Description

Anti mullerian hormone

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

11

Description

Leptin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

12

Description

Testosterone

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

13

Description

Sex hormone binding globulin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

ELISA Kit

14

Description

Insulin resistance

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

HOMA-IR

15

Description

Insulin sensitivity

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

QUICKI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ginger, 500 mg, 4 doses daily, for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo, 500mg, 4 doses daily, for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Endocrinology and Metabolism, Golestan hospital of ahvaz
Full name of responsible person
Zeinab Heidari
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Majid Mohammadshahi
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Golestan highway
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61357-15794
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shahi334@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Zeinab Heidari
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Email
Zeynab.heydari67@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
The total potential data can be shared after unidentifiable participant

When the data will become available and for how long
12 months after publication

To whom data/document is available
people working in academic institutions

Under which criteria data/document could be used
Confidential raw data for secondary analysis will be available to researchers.

From where data/document is obtainable
Zeinab Heidari zeynab.heydari67@gmail.com

What processes are involved for a request to access data/document
Submit a proposal from prestigious academic institution

Comments