

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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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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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

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Name of organization / entity

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Person responsible for updating data

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Name of organization / entity
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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