

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Metabolic Effects of Iranian Medicine-Based Diet in Women with Polycystic Ovarian Syndrome

Protocol summary

Study aim

Evaluation of Iranian Traditional medicine-based diet on anthropometric and metabolic factors

Design

Randomized controlled Clinical trial on 30 women with PCOs

Settings and conduct

Patients with PCOS are referred to the women's clinic of Taleghani Hospital which meets the inclusion criteria. After obtaining written consent, they will enter the study, then during 8 weeks, they will be randomly divided into the group receiving lifestyle modification recommendations and diet based on traditional medicine and the group receiving lifestyle modification recommendations. At the beginning and end of the study Anthropometric indicators of patients are measured and blood tests are also performed. Visiting and consulting patients is done separately and on different days

Participants/Inclusion and exclusion criteria

Women aged 28 to 42 with polycystic ovary syndrome, with a body mass index of 25 and above, who do not have diabetes, do not take hormonal and insulin regulatory drugs, do not have thyroid hormone disorders, hyperprolactinemia, and adrenal disorders.

Intervention groups

15 women with PCOs receive diet and recommendations for lifestyle modification 15 women with PCOs receive recommendations for lifestyle modification

Main outcome variables

FBS, insulin, HOMA, VAI, lipid profile, BMI, WHR

General information

Reason for update

Given the slow sampling process, calculations and revisions were performed by statisticians, and the sample size was adjusted based on previous similar studies. All steps were supervised by professors and approved by the faculty's educational council.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230627058594N1**
Registration date: **2023-09-01, 1402/06/10**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**

Update count: **1**

Registration date

2023-09-01, 1402/06/10

Registrant information

Name

Parivash Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

dr.p.qolami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

2024-09-22, 1403/07/01

Actual recruitment end date

2026-01-02, 1404/10/12

Trial completion date

2026-01-02, 1404/10/12

Scientific title

Metabolic Effects of Iranian Medicine-Based Diet in Women with Polycystic Ovarian Syndrome

Public title

Effect of Diet in Polycystic Ovarian Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with polycystic ovarian syndrome Body mass index ≥ 25

Exclusion criteria:

Diabetic patients Taking insulin-regulatory drugs Taking hormonal and supplemental drugs Thyroid hormone disorder Prolactin level disorder Adrenal disorder

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The population of eligible women is randomly assigned to two groups of at least 15 each, A and B, using a random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This study offers traditional-available foods for lifestyle modification and improvement of women with polycystic ovarian syndrome

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Science

Street address

Shahid Beheshti University of Medical Science, Sh. Arab Ave. Yaman Ave., Velenjak

City

Tehran

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Postal code

1985717443

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.115

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**

Body mass index

Timepoint

Before intervention and 2 months later

Method of measurement

Calculation

2**Description**

Waist circumference

Timepoint

Before intervention and 2 months later

Method of measurement

Tape measuring

3**Description**

Hip circumference

Timepoint

Before intervention and 2 months later

Method of measurement

Tape measuring

4**Description**

FBS

Timepoint

Before intervention and 2 months later

Method of measurement

Enzymatic method

5**Description**

Triglyceride

Timepoint

Before intervention and 2 months later

Method of measurement

Enzymatic method

6

Description

Serum HDL

Timepoint

Before intervention and 2 months later

Method of measurement

Enzymatic method

7

Description

Insulin

Timepoint

Before intervention and 2 months later

Method of measurement

Eliza

8

Description

FBS/fasting Insulin

Timepoint

Before intervention and 2 months later

Method of measurement

Calculation

9

Description

Visceral adiposity index

Timepoint

Before intervention and 2 months later

Method of measurement

Calculation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for 8 weeks, an Iranian traditional medicine-based diet is provided along with recommendations for lifestyle modification, and to follow the program, a telephone connection is made every 2 weeks.

Category

Lifestyle

2

Description

Control group: They receive lifestyle modification recommendations for 8 weeks

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Talegani hospital

Full name of responsible person

Parivash Gholami

Street address

Taleghani hospital, Velenjac, Shahid Chamran highway, Tehran

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taleghanihospital@sbm.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

7th floor, Bldg No.2 SBUMS, Arabi Ave, Velenjac, Tehran Shahid Beheshti University of Medical Sciences. No. 8. Shams Alley. In front of Tavanir Ave., Vali-Asr Ave

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Mpajouhesh@sbm.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parivash Gholami

Position

PhD Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Parivash Gholami

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Other areas of specialty/work

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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