

# 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  $\geq 25$

**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

**Province**

Tehran

**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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985711151

##### **Phone**

+98 21 2243 2558

##### **Fax**

+98 21 2243 2600

##### **Email**

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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

6941119839

##### **Phone**

+98 21 2243 9781

##### **Fax**

##### **Email**

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

**Street address**

Faculty of Traditional Shahid Beheshti University of Medical Sciences. No. 8. Shams Alley. In front of Tavanir Ave., Vali-Asr Ave

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**Postal code**

1516745811

**Phone**

+98 21 8877 3521

**Email**

dr.p.qolami@gmail.com

**Person responsible for scientific 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**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Parivash Gholami

**Position**

PhD student

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Medical doctor

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**Email**

dr.p.qolami@gmail.com

**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