

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effect of curcumin supplementation on glycemic control, antioxidant and anthropometric indices, PGC1- $\alpha$ and SIRT1 gene expression in polycystic ovary syndrome(PCOS) women

#### Protocol summary

##### Study aim

The effect of curcumin supplementation on glycemic control, antioxidant and anthropometric indices, PGC1- $\alpha$  and SIRT1 gene expression in polycystic ovary syndrome(PCOS) woman

##### Design

At the beginning of the study, the demographic information of participants (age, sex, education and diet weight loss) were completed by the researcher face to face. To assess the diet information, 3 of the 24-hour questionnaires were used (2 usual days and 1 day off) at the beginning and the end of the study. To evaluate the individual's physical activity, the International Short-Term Physical Activity Questionnaire (IPAQ) is used at the beginning and end of the study. Anthropometric measurements are performed at the beginning and end of the study. Ten cc blood samples will taken for biochemical factors assessment after 12-14 hours of fasting, at the beginning and the end of 90 days.

##### Settings and conduct

Patients with polycystic ovary syndrome referring to Arash Hospital, Tehran University of Medical Sciences are recruited in this study. participants randomly assigned to intervention and placebo group. participants, data gathering staff and statistical counselor will be blind of participants allocation

##### Participants/Inclusion and exclusion criteria

Women with polycystic ovaries based on Rotterdam diagnostic criteria and other endocrine disorders such as high prolactin levels, increased ovarian outer layer thickness, congenital adrenal hyperplasia, Cushing's syndrome, and orogenic or acromegaly producing tumors are considered for inclusion in this study.

##### Intervention groups

The intervention group received three capsules of 500 mg curcumin daily and control group receive three placebo capsules (maltodextrin) for 3 months.

#### Main outcome variables

PGC1- $\alpha$  gene expression; Sirt1 gene expression; GPx Serum levels; Serum concentration of SOD; Serum concentration of LH; Serum FSH concentration; Serum DHEA levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091114002709N50**  
Registration date: **2019-01-23, 1397/11/03**  
Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

##### Registration date

2019-01-23, 1397/11/03

##### Registrant information

##### Name

Farzad Shidfar

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8862 2755

##### Email address

shidfar.f@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-07-23, 1398/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of curcumin supplementation on glycemic control, antioxidant and anthropometric indices, PGC1- $\alpha$  and SIRT1 gene expression in polycystic ovary syndrome(PCOS) women

**Public title**

Curcumin in PCOS

**Purpose**

Basic science

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The willingness to voluntarily participate in the study  
Diagnosis of polycystic ovary syndrome by a specialist physician in the mild to moderate phase  
Having impaired glucose tolerance (IGT)  
The consumer is just one of the metformin or clomiphene drug groups  
Age more than 18 years old  
BMI higher than 25 and less than 30 kg/m<sup>2</sup>

**Exclusion criteria:**

Change the type and dosage of the drug over the past month  
Congenital hormonal disorders, autoimmune diseases, cancer, inflammatory diseases, hyperthyroidism and hypothyroidism, infections, pregnancy or lactation in women, or use of contraceptive pills  
The use of multi-vitamin-mineral, omega-3, polyphenolic and antioxidant supplements, as well as the use of anticoagulants such as heparin and warfarin or aspirin, blood cholesterol-lowering drugs (statins), NSAIDs, such as ipobrofen, aspirin and diclofenac, Antihistamines, calcium channel antagonists such as nifedipine, anti-TNF drugs (infliximab, adalimumab and cinnura), glucocorticosteroids (cortisone, prednisolone) and spironolactone during in the past month.

**Age**

From **18 years** old to **50 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Our sample size is 72 subjects in two groups of 36 participants in each group. Block randomization method was designed using statistical software Stata Version 13.

The number of blocks considered is 6.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The random allocation list will be provided only to the statistical consultant. To hide the random allocation process, there are 72 paper labels with randomized 10-digit random codes and a specific frame that identifies the relevant treatment and will be the only methodologist of the design of the code. Labels will be arranged in random order on the drug packs. The drug packs will be arranged in a randomized random list. When the physician announces the eligibility of a patient, the methodologist will provide the package patient with the package. The person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. To analyze the data, a statistician who is separate from the study process and who is unaware of all the processes performed will be used.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-10-28, 1397/08/06

**Ethics committee reference number**

IR.IUMS.REC.1397.690

**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**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

laboratory kit

### 2

#### **Description**

Fasting Insulin

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

laboratory kit

### 3

#### **Description**

PGC1- $\alpha$  gene expression

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

Real Time RT-PCR

### 4

#### **Description**

Sirt1 gene expression

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

Real Time RT-PCR

## Secondary outcomes

### 1

#### **Description**

Serum GPx

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

laboratory kit

### 2

#### **Description**

Serum SOD

### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

### **Method of measurement**

laboratory kit

### 3

#### **Description**

Serum Concentration of DHEA hormone

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

laboratory kit

### 4

#### **Description**

Serum concentration of LH

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

laboratory kit

### 5

#### **Description**

serum Concentration of FSH hormone

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

laboratory kit

### 6

#### **Description**

Insulin resistance

#### **Timepoint**

At the beginning of the study (before the intervention) and the end of the study (3 months after the intervention)

#### **Method of measurement**

Computing

## Intervention groups

### 1

#### **Description**

Intervention group: Curcumin (Turmeric Extract) in 500 mg capsules (manufactured by Karen Company, Iran) three times a day for three months

#### **Category**

Treatment - Drugs

## 2

### Description

Control group: Placebo (Maltodextrin) with the same shape and design and color of the main intervention in 500 mg capsules

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Arash hospital

##### Full name of responsible person

Javad Heshmati

##### Street address

West 162 alley, Baghdarnia Street, East Farjam Street, Bagheri Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1751656363

##### Phone

+98 21 7788 3283

##### Fax

+98 21 7788 3196

##### Email

hosp\_arash@tums.ac.ir

##### Web page address

<http://arash.tums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyed Kazem Malakouti

##### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

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##### Province

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##### Phone

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##### Email

ivco@iums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Farzad Shidfar

##### Position

Professor of Nutrition

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

##### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Farzad Shidfar

##### Position

Professor of Nutrition

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

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##### Province

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
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professor of nutrition  
**Latest degree**  
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**Other areas of specialty/work**  
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+98 21 8862 2755  
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+98 21 8862 2533  
**Email**  
shidfar.f@iums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more information

### 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

No - There is not a plan to make this available

### Clinical Study Report

No - There is not 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

### Title and more details about the data/document

The primary outcome is the capable to share at the end of the study

### When the data will become available and for how long

Start the access period 6 months after publishing the results

### To whom data/document is available

Researchers working in academic institutes

### Under which criteria data/document could be used

By requesting the correspond, there will be the possibility of using the data

### From where data/document is obtainable

Professor Farzad Shidfar School of Public Health Iran University of Medical Science Hemmat, and Chamran Highways crossroad Tehran Iran. Tel: +98 21 86704743 Cell: +98 9123082922 Fax: +98 21 88622707 Email: shidfar.f@iums.ac.ir Additional email: farzadShidfar@yahoo.com

### What processes are involved for a request to access data/document

When, an email sent to the correspond author, the data will usually be sent within 5 to 10 business days

### Comments