

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of apple cider vinegar tablet on metabolic syndrome and insulin resistance in PCOS patients: A randomized double-blind trial

#### Protocol summary

##### Study aim

The effect of apple cider vinegar tablet on metabolic syndrome and insulin resistance in polycystic ovary syndrome patients

##### Design

A randomized, double-blind, placebo-controlled clinical trial with control group in parallel with a calculated sample size of 47 patients in each group totaling 94 patients.

##### Settings and conduct

Samples were selected from women referring to the infertility clinic of Arash Women General Hospital who met the inclusion criteria and were randomly assigned to one of two intervention or control groups. The intervention duration is 12 weeks and these patients will be evaluated at the beginning of the study and at the end of the twelfth week.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 15 to 49 years- Iranian nationality- willing to participate in the study- not pregnant- have at least literacy for read and write- no Mellitus Diabets according to primary FBS- no chronic diseases affecting the polycystic ovary syndrome - lack of consumption Anti lipids and Anti hypertensive and anti coagulative drugs during the last three months/ Exclusion criteria: occurrence of any side effects caused by medication and intervention- unwillingness to continue participation - failure to comply with treatment protocol

##### Intervention groups

Intervention group: Apple cider vinegar tablets 500 mg three times daily for 12 weeks with other medications/ Control group: Apple cider vinegar placebo in the same dose and form for 12 weeks.

##### Main outcome variables

Plasma Level of FBS/Insulin/Triglyceride/Cholesterol total/ LDL/ HDL/ Testosterone/ Level of systolic and diastolic blood pressure/ Weight/ Waist-to-hip ratio (WHR)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150905023897N7**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

##### Registration date

2023-12-11, 1402/09/20

##### Registrant information

##### Name

Dr. Shahideh Jahanian Sadatmahalleh

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 4826

##### Email address

shahideh.jahanian@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-01, 1402/08/10

##### Expected recruitment end date

2024-05-21, 1403/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of apple cider vinegar tablet on metabolic syndrome and insulin resistance in PCOS patients: A randomized double-blind trial

## Public title

The effect of apple cider vinegar tablet on metabolic syndrome and insulin resistance in PCOS patients: A randomized double-blind trial

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

fertility age between 15-49 years Iranian women No pregnancy Have at least literacy for read and write No Mellitus Diabets according to primary FBS No chronic diseases affecting PCOS (such as congenital adrenal hyperplasia, Cushing's syndrome, hyperprolactinemia, thyroid dysfunction) Lack of consumption Anti lipids and Anti hypertensive and anti coagulative drugs during the last three months People are willing to participate in the study

### Exclusion criteria:

People with drug side effects Individuals unwilling to continue to participate in the study failure to comply with treatment protocol

## Age

From **15 years** old to **49 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **94**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, we will use the restricted randomization method (block randomization type). Blocking is often with the purpose Creating a balance in the number of samples assigned to each of the studied groups should be used. This feature allows researchers to have the same number of samples assigned to each of the studied groups in cases where intermediate analyzes are needed during the sampling process. The size of all the blocks is equal and we will have 4 blocks in this two-group experiment (including 2 participants in the intervention group and 2 participants in the control group). The randomization tool is also used from random sequence generation software (random allocation software), which in addition to simple randomization, these random sequence generation software are also capable of generating random sequence by block method. In order to conceal, we will use Concealment Allocation, which refers to the method used to perform a random

sequence on the participants in the study, so that the allocated group is not known before the allocation of the individual. By using sealed and non-transparent envelopes with a random sequence (envelopes opaque, sealed, numbered Sequentially (in this method, each of the random sequences created on a registration card, and the cards inside the letter envelopes) They are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Then the lid of the letter envelopes is glued and placed in a box in order. At the time of the registration of the participants, based on the order of entry of the qualified participants into the study, one of the envelopes will be opened in order and the assigned group of that participant will be determined.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The researcher and patient will be unaware of the treatment and grouping of the study. For this purpose, apple cider vinegar tablet and placebo are coded by a research center. The lead researcher treats patients in a double-blind manner based on the drug package code. The code for the drug package is recorded on the personal information form, and the researcher who completes the information form will not be informed of the type of treatment.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tarbiat Modares university

#### Street address

Jalal E Al Ahmad

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۱۱۷۱۳۱۱۶

### Approval date

2023-10-30, 1402/08/08

### Ethics committee reference number

IR.MODARES.REC.1402.109

## Health conditions studied

1

### Description of health condition studied

Metabolic syndrome in PCOS patients

**ICD-10 code**

**ICD-10 code description**

**2**

**Description of health condition studied**

Insulin resistance in PCOS patients

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Blood level of FBS

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test

**2**

**Description**

Blood level of Insulin

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test

**3**

**Description**

Level of Triglyceride

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test

**4**

**Description**

level of total cholesterol

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test

**5**

**Description**

blood level of LDL

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test

**6**

**Description**

blood level of HDL

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test

**7**

**Description**

blood level of testosterone

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test

**8**

**Description**

weight

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

use of scale

**9**

**Description**

Waist to hip ratio

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Use of meter

**10**

**Description**

Level of systolic and diastolic blood pressure

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Use of mercury barometer

**Secondary outcomes**

**1**

**Description**

Menstrual dysfunction such as: Oligomenorrhea and amenorrhea

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Patient statements

**2**

**Description**

Clinical hyperandrogenemia

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Blood biochemistry test and clinical symptom

### 3

**Description**

Ultrasound view of the ovaries

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

Use of ultrasound

### 4

**Description**

Sexual function

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

FSFI questionnaire

### 5

**Description**

Quality Of life

**Timepoint**

First of study and 12 weeks after intervention

**Method of measurement**

MPCOSQ questionnaire

## Intervention groups

### 1

**Description**

Intervention group: Treatment by Apple cider vinegar tablet 500 mg

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Treatment by placebo of Apple cider vinegar tablet

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Arash hospital

**Full name of responsible person**

Shahideh Jahanian Sadatmahalleh

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Shahid baghdarnia Ave

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tarbiat modares University

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pres@modares.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tarbiat modares University

**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**

Tarbiat modares University

**Full name of responsible person**

Shahideh Jahanian Sadatmahalleh

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Position**

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Ph.D.  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

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

Information on the main outcome of the study

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

1403

### To whom data/document is available

Academic researchers

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

Use for further research in the future

### From where data/document is obtainable

Email Addressing Responsible for Study

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

Submit a request to study and follow up

### Comments