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
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Iran (Islamic Republic of)
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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 testostrone

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
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Sponsors / Funding sources

1

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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
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
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Shahideh Jahanian Sadatmahalleh
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Associate Professor
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Person responsible for updating data

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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