Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The survery of Turmeric Extract effect on Serum Adiponectin Levels and the FerrimanGallwey Scoring System of Hirsutism in PCOS Women; a Randomized Double-blind ClinicalTrial

Protocol summary

Study aim
Use of turmeric extract in patients with polycystic ovary syndrome

Design
A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct
A placebo-controlled randomized double-blind clinical trial Women of reproductive age between 18 and 35 years with PCOS referred to gynecology and endocrinology and infertility clinics Tehran and Alborz hospitals. Sampling Method: After obtaining informed consent by purposeful sampling among women with PCOS who volunteered at the centers And will meet the inclusion criteria.

Participants/Inclusion and exclusion criteria
Age range 35-18 years Be Iranian and Persian language. Satisfaction of the person to enter the study Without any history of abortion and cesarean delivery No medical problems such as diabetes and high blood pressure, psychological diseases, infections and other pelvic pathologies and other medical problems. Have spent the past six months without severe psychological stress Diagnosis of polycystic ovary syndrome based on Rotterdam criteria and approval by a gynecologist Hirsutism No alcoholism and no history of alcohol and drug use The diet is normal.

Intervention groups
People in the study will be divided into two groups. The intervention in the PCOS target group will be using the usual treatment (metformin) with turmeric extract for 8 weeks at a rate of 100 kg / mg. In the control group, PCOS patients will use the usual treatment (metformin) and placebo.

Main outcome variables
Serum adiponectin level؛ The state of hirsutism

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191126045514N1**
Registration date: **2021-02-14, 1399/11/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-14, 1399/11/26**
Update count: **0**

Registration date
2021-02-14, 1399/11/26

Registrant information

Name
MOBARAKEH MAZAREEI

Name of organization / entity
TARBIAT MODARES UNIVERSITY

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-30, 1398/10/09

Expected recruitment end date
2021-09-19, 1400/06/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The survery of Turmeric Extract effect on Serum Adiponectin Levels and the FerrimanGallwey Scoring System of Hirsutism in PCOS Women; a Randomized Double-blind ClinicalTrial

Public title
The effect of turmeric on the treatment of women with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 35-18 years Be Iranian and Persian language Satisfaction of the person to enter the study Without any history of abortion and cesarean delivery No medical problems such as diabetes and high blood pressure, psychological diseases, infections and other pelvic pathologies and other medical problems. Have spent the past six months without severe psychological stress Diagnosis of polycystic ovary syndrome based on Rotterdam criteria and approval by a gynecologist No alcoholism and no history of alcohol and drug use The diet is normal.

Exclusion criteria:
A person with polycystic ovary disease is taking a drug other than metformin

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization of an individual with an envelope in dividing the groups into two groups A and B. In this method, we selected a number of cards or letters as the intervention group and the same number of cards for the control group, then merged the cards together. One card was taken out and its allocation was recorded, and after the card was taken out, we returned it again to all the other cards. Then the cards are merged again and we take out another card. This process continues until a random sequence is reached according to the sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is a double-blind study and the researcher and the patient will be unaware of the treatment and grouping of the study. For this purpose, turmeric extract and placebo are encoded by a third party. The main researcher intervenes patients in a double-blind manner based on the code of drug packages. The drug code is recorded on the demographic information completion form. Intervention in the PCOS target group will be using the usual treatment (metformin) with turmeric extract for 8 weeks at a rate of 100 kg / mg Placebo will be prepared in a similar way to turmeric extract without its effective ingredients. 8 weeks after using turmeric extract, again in women of both groups A venous blood sample will be taken.

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
Tehran jalal al ahmad Ave tarbiat modares university

City
TEHRAN

Province
Tehran

Postal code
111-14115

Approval date
2019-12-29, 1398/10/08

Ethics committee reference number
IR.MODARES.REC.1398.175

Health conditions studied

1

Description of health condition studied
PCOS

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Serum adiponectin levels

Timepoint
Befor and 8 WEEKS After intervention

Method of measurement

Blood Test

2

Description
Hirsutism status based on Freeman Galloway score
Timepoint
Befor and 8 WEEKS After intervention
Method of measurement
View and score based on Freeman Galloway score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The usual treatment (metformin) with turmeric extract will be 100 mg / kg for 8 weeks. This article has been extracted and concentrated by Dr. Elaheh Sadeghi under the supervision of Dr. Mohsen Sharifi, Professor, Department of Plant Physiology, Faculty of Basic Sciences, Tarbiat Modarres University, Iran
Category
Treatment - Drugs

2

Description
Control group: the usual treatment (metformin) and placebo, Placebo will be prepared in a similar way to turmeric extract without its effective ingredients. 8 weeks after using , women in both groups will have venous blood sampling again.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash hospital
Full name of responsible person
Mobarakeh Mazareei
Street address
NO. 162 , Shahid Baghdarnia Ave (North Rashid), Behind Shahid Bagheri Highway ,Resalat Highway
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Province
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Phone
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Fax
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hosp_arash@tums.ac.ir
Web page address
http://arash.tums.ac.ir/contact/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat modares University
Full name of responsible person
Najmeh Tehranian
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Phone
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Email
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
Najmeh Tehranian
Position
PHD
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
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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
Only part of the information

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Scientific and research studies

From where data/document is obtainable
Mobarakeh.mazareei@modares.ac.ir
mobarakeh72mazareei@gmail.com

What processes are involved for a request to access data/document
one week until one month

Comments