

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The survey 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)

Phone

+98 21 7678 0471

Email address

mobarakeh.mazareei@modares.ac.ir

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 survey of Turmeric Extract effect on Serum Adiponectin Levels and the FerrimanGallwey Scoring System of Hirsutism in PCOS Women; a Randomized Double-blind Clinical Trial

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

Before and 8 WEEKS After intervention

Method of measurement

Blood Test

2

Description

Hirsutism status based on Freeman Galloway score

Timepoint

Before 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

City

Tehran

Province

Tehran

Postal code

1448634443

Phone

+98 21 7788 3284

Fax

Email

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

Street address

tehran jalal al ahmad ave

City

Tehran

Province

Tehran

Postal code

111-14115

Phone

+98 21 8800 6544

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

Street address

Tehran, Jalal Al Ahmad, Paul Nasr, Tarbiat Modarres University

City

TEHRAN
Province
Tehran
Postal code
111-14115
Phone
+98 21 8800 6544
Email
tehranian@modares.ac.ir

Person responsible for scientific 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
Street address
Tehran, Jalal Al Ahmad, Paul Nasr, Tarbiat Modarres University
City
tehran
Province
Tehran
Postal code
111-14115
Phone
+98 21 8800 6544
Email
tehranian@modares.ac.ir

Person responsible for updating data

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
Street address
Tehran, Jalal Al Ahmad, Paul Nasr, Tarbiat Modarres University
City
TEHRAN
Province
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Postal code
111-14115
Phone
+98 21 8800 6544
Email
tehranian@modares.ac.ir

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