

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of saffron petal capsule on the monthly cycle pattern and symptoms of clinical and biochemical hyperandrogenism in women with polycystic ovary syndrome

Protocol summary

Study aim

Determining the effect of saffron petal capsules on the monthly cycle pattern and clinical and biochemical hyperandrogenism symptoms in women with polycystic ovary syndrome.

Design

A placebo-controlled, three-blind, randomized phase 2 clinical trial on 80 patients will be used for randomization using PASS version 11 software

Settings and conduct

Place of study: women's clinics of educational hospitals in Mashhad; Study population: 80 women referring to women's clinics of educational hospitals in Mashhad; Type of blinding: three blinds; How to blind: saffron petal capsules and placebo will be put in completely similar capsules and cans, which are similar in shape and color, and only the pharmacist consultant will know about the assigned codes

Participants/Inclusion and exclusion criteria

Women of reproductive age (15-45 years), with pcos according to Rotterdam criteria, normal puberty, normal thyroid test, low FSH level; Non-entry: Suffering from certain medical diseases, having a history of surgery, having a history of laser treatment in the upper lip, chin, chest and lower abdomen and drug treatment in the last two months, having an allergy to saffron and its petal medicines, smoking and Hookah, suffering from premature menopause

Intervention groups

Intervention group: 30 mg capsules of saffron petals made in the pharmacology department of medicinal plants of Mashhad University of Medical Sciences will be used daily for 3 months. Control group: A placebo capsule containing Avicel made in the Pharmacology Department of Medicinal Plants of Mashhad University of Medical Sciences will be used once a day for 3 months.

Main outcome variables

Menstrual cycle pattern, clinical and biochemical symptoms of hyperandrogenism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240414061487N1**

Registration date: **2024-04-21, 1403/02/02**

Registration timing: **prospective**

Last update: **2024-04-21, 1403/02/02**

Update count: **0**

Registration date

2024-04-21, 1403/02/02

Registrant information

Name

Fatemeh Feizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

Email address

feizif4012@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-04, 1403/02/15

Expected recruitment end date

2024-08-04, 1403/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of saffron petal capsule on the monthly cycle pattern and symptoms of clinical and biochemical hyperandrogenism in women with polycystic ovary syndrome

Public title
Effect of saffron petals in treatment of polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women of reproductive age (15-45 years old) of Iranian descent fluent in Persian Literate to read and write receiving and signing written consent suffering from pcos according to Rotterdam criteria normal puberty normal thyroid test low FSH levels
Exclusion criteria:
Having medical diseases (heart, liver, digestive and kidney, diabetes, blood pressure) having a history of surgery in the last two months having a history of laser in the area of the upper lip, chin, chest and lower abdomen in the last two months drug treatment (antidiabetic drugs such as insulin, antihypertensive drugs, Sedative) in the last two months being allergic to saffron and its petal medicines using cigarettes and hookah suffering from premature menopause

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly assign eligible people to two groups, we use four and two combined blocks, for this assignment we use PASS version 11 software. By generating random numbers, this software creates 4-long blocks of letters A and B that have two A's and two B's. We put these letters together and number them from 1 to 80 and put each letter in an envelope and write its number on the envelope. which we put inside are allocated

Blinding (investigator's opinion)
Triple blinded

Blinding description
1. Using a placebo that is completely similar to the saffron petal capsule in terms of shape, color and size. 2.

After allocating the people, the relevant group will be placed inside the sealed envelope, which will be assigned to two groups in order of entry

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Nursing and Midwifery, Mashhad University of Medical Sciences
Street address
Nursing and Midwifery School , Shahid Dr. Kharazmi Educational Building, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177949025

Approval date
2024-03-04, 1402/12/14

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.138

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
Menstrual cycle pattern

Timepoint
Before the study and 3 months after the intervention

Method of measurement
Questionnaire made by the researcher on the pattern of menstrual cycle

2

Description

Hirsutism
Timepoint
Before the study and 3 months after the intervention
Method of measurement
Freeman Galloway form

3

Description
Symptoms of biochemical hyperandrogenism
Timepoint
Before the study and 3 months after the intervention
Method of measurement
Taking a blood sample

4

Description
Acne
Timepoint
Before the study and 3 months after the intervention
Method of measurement
Global Acne Grading system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 mg capsules of saffron petals made in the pharmacology department of medicinal plants of Mashhad University of Medical Sciences will be used daily for 3 months.

Category
Treatment - Drugs

2

Description
Control group: A placebo capsule containing Avicel made in the Pharmacology Department of Medicinal Plants of Mashhad University of Medical Sciences will be used once a day for 3 months.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Women's clinics of teaching hospitals in Mashhad
Full name of responsible person
Fatemeh Erfanian Arghavani
Street address
Nursing and Midwifery School , Martyr Dr. Kharazmi Educational Building, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mahmood Shabestary
Street address
Nursing and Midwifery School , Martyr Dr. Kharazmi Educational Building, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square
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Mashhad
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Postal code
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nms.pr@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Feizi
Position
student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Nursing and Midwifery School , Shahid Dr. Kharazmi Educational Building, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square

City

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Erfanian Arghavani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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