Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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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

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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

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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

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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