

# 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

Menstrual cycle pattern, clinical and biochemical symptoms of hyperandrogenism

#### 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

#### 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)

###### Phone

+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

**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913199  
**Phone**  
+98 51 3859 1511  
**Email**  
ErfanianF@mums.ac.ir

## 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  
**City**  
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**Province**  
Razavi Khorasan  
**Postal code**  
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**Phone**  
+98 51 3859 1511  
**Email**  
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

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**Email**

FeiziF4012@mums.ac.ir

**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

**Street address**

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**Email**

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**Person responsible for updating data****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**

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**City**

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**Province**

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**Phone**

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**Email**

FeiziF4012@mums.ac.ir

**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