Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of therapeutic effects of crocina (saffron tablets) in patients with polycystic ovary syndrome: a randomized double-blind clinical trial

Protocol summary

Study aim

1) Determine the effect of crocin consumption on hirsutism in patients with PCOS 2) Determine the effect of crocin consumption on acne in patients with PCOS 3) Determine the effect of crocin intake on body mass index in patients with PCOS 4) Determine the effect of crocin consumption on menstrual disorder in patients with PCOS 5) Determination of the effect of crocin on laboratory parameters of FBS, LH, DHEA, FSH in patients with PCOS

Design

Fifty patients with confirmed PCOS and known hirsutism will be studied by the Rotterdam Criteria. Patients take 15 mg crocina tablets once daily, or placebo tabletsfor 12 weeks to complete three full cycles of menstruation.

Settings and conduct

Baghaeipour and Khatam Al-Anbia Clinic in Yazd

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age 18 to 44 years 2) A well-known patient with polycystic ovary syndrome 3) Adequate literacy to understand the study, drug use and potential side effects Exclusion criteria: 1) drug intolerance 2) Not taking the medicine correctly 3) Serious medical conditions that the patient cannot regularly attend periodic visits including severe cardiovascular disease such as angina or myocardial infarction, recent stroke, psychiatric disorders, active concussion, and anemia 4) Use estrogenic or progestin drugs to regulate the monthly cycle 5) Use of antidepressants including SSRI, SNRI, TCA, MAOI 6) Failure to sign a written consent 7) Pregnancy and lactation

Intervention groups

Patients will be randomly divided into two groups of recipients including the first group (metformin and placebo) and the second group (combination of crosina and metformin) (25 patients each)

Main outcome variables

Changes in serum levels of FBS, gonadotropins (LH and FSH), dihydroepiandrosterone dione

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210730052027N1**
Registration date: **2021-08-26, 1400/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-26, 1400/06/04**
Update count: **0**

Registration date

2021-08-26, 1400/06/04

Registrant information

Name

Ahdie Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5366 6426

Email address

asadiahdie@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-16, 1400/05/25

Expected recruitment end date

2022-08-16, 1401/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of crocina (saffron tablets) in patients with polycystic ovary syndrome: a randomized double-blind clinical trial

Public title

Evaluation of therapeutic effects of crocina (saffron tablets) in patients with polycystic ovary syndrome: a randomized double-blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 44 years Adequate literacy to understand the study, drug use and potential side effects Patient known with polycystic ovary syndrome

Exclusion criteria:

Serious medical conditions that the patient cannot regularly attend periodic visits include severe cardiovascular disease such as angina or myocardial infarction, recent stroke, psychiatric disorders, active concussion, and anemia Taking estrogenic or progestin drugs to regulate the monthly cycle Antidepressants (SSRI, SNRI, TCA, MAOI6) Failure to sign written consent Pregnancy and lactation

Age

From **18 years** old to **44 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 50 patients are randomly allocated into two treatment groups (A and B). Block randomization method will be used for random allocation. Ten blocks of five are considered. The generated permutations include the letters A and B, which are repeated (for example, ABAAB) in each permutation. These permutations are generated using Random allocation software version 1. For this purpose, the generated list by the software is from 1 to 50, which are arranged in 10 blocks of five in order. To run this software output, we give the first qualified person number 1 and the last person will receive number 50. To consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is asked and thus people enter the study. In addition, in the software output, both numbers 1 to 50 and the permutations of the letters A and B can be seen

Blinding (investigator's opinion)

Double blinded

Blinding description

All stages will be covered by the patient, physician, and evaluator. The first presenter identifies the sequence of assignment of patients according to the order of entry of the patients to the study and places the drugs in a uniform envelope and identifies them with A or B codes. He then identifies the medications that are appropriate for each individual according to the above description and puts them in special envelopes and delivers them to patients.

Placebo

Used

Assignment

Parallel

Other design features

All patients who enter this study will fill out and sign the consent form. A questionnaire will be designed to provide information on patients' conditions, and all patients will be asked all questions regarding entry and exit conditions. Based on this and consultation with the physician to decide on entry or exit of patients. After identifying and selecting patients, they receive written consent (after explaining its content to the student) and eligible patients enter the phase. They will be randomly assigned to the study to receive one of the interventions. patients will be selected by referrals to the Women's Clinic of Shahid Rahnemoon Hospital in Yazd and will be randomly assigned

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

faculty of ethics of medical sciences - shahid sadoughi university of medical sciences

Street address

Gomnam shohada boulevard - shahid sadoughi university of medical sciences

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.220

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

Changes in Serum Levels of Gonadotropins (LH and FSH) Dihydroepiandrosterone Dione (DHEA) Fasting Blood Glucose

Timepoint

Before the intervention, after completion of the intervention

Method of measurement

Blood sample

2

Description

Measuring fasting blood sugar

Timepoint

Before the intervention, after completion of the intervention

Method of measurement

Blood sample

3

Description

Changes in Serum Levels of Dihydroepiandrosterone Dione (DHEA)

Timepoint

Before the intervention, after completion of the intervention

Method of measurement

Blood sample

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before the intervention, after completion of the intervention

Method of measurement

Based on the Body Mass Index

2

Description

Hirsutism

Timepoint

At the beginning of the study and at 15,30,45,60,75,90 days after the intervention

Method of measurement

Clinical case and Ferriman-Galwey criteria and also subjectively as a patient self-report for improved hirsutism with the modified (Dermatology Quality of Life Index)

Intervention groups

1

Description

Intervention group: 25 patients diagnosed with PCOS based on the Rotterdam Criteria will take 15 mg of Crosina (Saffron as an active ingredient) once a day and metformin 500 mg three times a day for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: 25 patients diagnosed with PCOS based on the Rotterdam Criteria will take a placebo of Crosina tablet once a day and metformin 500 mg three times a day for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Atiyeh Javaheri

Street address

Shahid Sadoughi General Hospital

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۴۹

Phone

+98 35 3626 0001

Email

atiyeh56@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohamad Reza Mirjalili

Street address

Bahonar Square

City

Yazd

Province

Yazd

Postal code

8916978477

Phone
+98 35 3724 1171

Fax
+98 35 3724 1171

Email
ravabet@SSU.AC.IR

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Ahdieh Asadi

Position
University student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

Street address
ایران، یزد، بلوار پروفسور حسابی

City
Yazd

Province
Yazd

Postal code
۸۹۱۵۱۷۳۱۴۹

Phone
+98 35 3820 3419

Email
asadiahdie@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Saghafi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Professor Hesabi Blvd., Yazd Province, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
۸۹۱۵۱۷۳۱۴۹

Phone
+98 35 3820 3419

Email
F.saghafi@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Saghafi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Professor Hesabi Blvd., Yazd Province, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
۸۹۱۵۱۷۳۱۴۹

Phone
+98 35 3820 3419

Email
F.saghafi@ssu.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