Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The Effect of Evening Primrose Oil on Clinical Symptoms in Women with Polycystic Ovary Syndrome: A Randomized Controlled Trial

Protocol summary

Study aim
To determine the effect of evening primrose on clinical symptoms in women with polycystic ovary syndrome

Design
Clinical trial with a control group, with parallel groups, triple blinded, randomized with blocking method, phase three on 62 patients. The randomizer software will be used for randomization.

Settings and conduct
This study will be performed in Al-Zahra, Taleghani, Imam Reza and Sina Educational-Medical Centers of Tabriz. Participants in the intervention group will receive 1000 mg evening primrose oil capsules daily and the participants in the control group will receive placebos capsule similar to the intake order for intervention group. The duration of the intervention will be 12 weeks. Hirsutism, depression and menstrual characteristics questionnaires will be completed before and after the end of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmation of the diagnosis of PCOS according to the criteria of Androgen Excess/PCOS Society; Minimum hirsutism score of 6 based on the Freeman Galloway criterion; Having reading and writing literacy; BMI between18.5 and 40; Not taking vitamins, minerals and omega-6 in the three months before the intervention Exclusion criteria: Having other androgenic disorders; Cushing's syndrome; Having thyroid gland diseases; Pregnancy or breastfeeding; Infertility treatment at the time of study; Previous surgery on one or both ovaries; Consumption of pharmaceutical food supplements; Smoking and alcohol consumption; Occurrence of unfortunate events

Intervention groups
Participants in the intervention group will receive 1000 mg evening primrose oil capsules daily and the participants in the control group will receive one placebo capsule similar to the intake order for intervention group. The duration of the intervention will be 12 weeks.

Main outcome variables
Hirsutism and depression symptoms score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N73**
Registration date: **2022-11-08, 1401/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-08, 1401/08/17**
Update count: **0**

Registration date
2022-11-08, 1401/08/17

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-21, 1401/07/29

Expected recruitment end date
2023-04-19, 1402/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Evening Primrose Oil on Clinical Symptoms in Women with Polycystic Ovary Syndrome: A Randomized Controlled Trial

Public title

The Effect of Evening Primrose Oil on Clinical Symptoms in Women with Polycystic Ovary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of the diagnosis of PCOS according to the criteria of the Androgen Excess/PCOS Society, including anovulation, chronic low ovulation, or polycystic ovaries and clinical or biochemical signs of hyperandrogenism Minimum hirsutism score of 6 with the Freeman Galloway criterion Having literacy to complete the questionnaires BMI between 18.5 and 40 Ages 18-45 years Not taking vitamins, minerals and omega-6 in the three months before the intervention

Exclusion criteria:

Having other androgenic disorders such as adrenal hyperplasia or androgen-producing tumor Having Cushing's syndrome Having thyroid gland diseases Pregnancy or breastfeeding Women undergoing infertility treatment at the time of the study Previous surgery on one or both ovaries Consumption of dietary supplements Smoking and alcohol consumption Occurrence of unfortunate events

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be assigned to two groups (one group receiving evening primrose capsules and one group receiving placebo capsules with the same protocol) by block randomization method with block sizes of 4 and 6 and a allocation ratio of 1: 1. To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer software, and the evening primrose oil or placebo capsules will be placed in the same packages numbered sequentially.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants, researcher and data analyst will be blinded in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

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Approval date

2022-10-07, 1401/07/15

Ethics committee reference number

IR.TBZMED.REC.1401.599

Health conditions studied

1

Description of health condition studied

Polycystic Ovary Syndrome (PCOS)

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Hirsutism score

Timepoint

Before the intervention and after the end of intervention

Method of measurement

Ferriman – Gallwey index

2

Description
Depression symptoms score
Timepoint
Before the intervention and after the end of intervention
Method of measurement
Beck Depression Inventory

Secondary outcomes

1

Description
Frequency of adverse events in the study groups
Timepoint
During the intervention
Method of measurement
Researcher-made checklist

2

Description
Anthropometric indices (waist circumference, hip circumference, BMI)
Timepoint
Before and after the intervention
Method of measurement
Checklist of anthropometric indices

3

Description
Menstrual disorders
Timepoint
Before and after the intervention
Method of measurement
Menstrual characteristics questionnaire

Intervention groups

1

Description
Intervention group: For each person three matte container including 30 1000 mg evening primrose oil capsules will be prepared with a certain number. At the beginning of the study, a container including evening primrose oil will be given to the patients, and after the end of the first month, the second container will be given to the participants for consumption in the second month and the third c for container consumption in the third month will be given at the end of the second month. The treatment period will continue for three months. The intake method of evening primrose oil capsules is taking of one capsule a day with a glass of water.
Category
Treatment - Drugs

2

Description
Control group: For each person three matte container including 30 1000 mg placebo capsules will be prepared with a certain number. At the beginning of the study, a container including placebo will be given to the patients, and after the end of the first month, the second container will be given to the participants for consumption in the second month and the third c for container consumption in the third month will be given at the end of the second month. The treatment period will continue for three months. The intake method of placebo capsules is taking of one capsule a day with a glass of water.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
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2

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3

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Name of recruitment center
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4

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Sponsors / Funding sources

1

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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
Tabriz 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

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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
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
Undecided - It is not yet known if there will be 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