Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating The Effect Of Ferula assa-foetida On The Quantity And Quality Of Eggs In Infertile Women With polycystic ovaries

Protocol summary

Study aim

Main objectives: Determining the effect of Ferula assa-foetida on the quantity and quality of eggs in infertile women with PCO

Design

A phase 3, double-blind, randomized, controlled clinical trial on 72 patients, using four-way alternating blocks for randomization.

Settings and conduct

This research will be a randomized, double-blind clinical trial with two intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 1. Women aged 18 to 40 years 2. History of primary or secondary infertility 3. Diagnosis of polycystic ovary syndrome based on the opinion of a specialist doctor 4. No known mental illness or any illness that affects the fertility process. 5. Normal fallopian tubes. 6. The absence of infertility in the spouse, according to the doctor's approval. Exclusion criteria include: 1. Women who are discouraged from continuing to participate in the study for any reason. 2. Causing any complications during treatment with Ovla Mom capsules that are in conflict with pregnancy.

Intervention groups

The intervention includes the daily consumption of two Ovalamam capsules, each containing 500 mg of oleogum resin from the plant Ferula assa-foetida, and the control group will be prescribed two capsules daily, each capsule will be in the form of capsules similar and of the same weight as the Ovalamam capsules and will contain bread powder, which will be encapsulated at the Clinical Trial Research Center of Traditional Medicine at Shahed University.

Main outcome variables

If this herbal product achieves a positive effect on the symptoms of polycystic ovary syndrome and infertility, by providing its results to women's and mothers' health officials, it will improve the health of women and subsequently the entire family, as well as reduce consumer costs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241127063875N1**
Registration date: **2025-01-02, 1403/10/13**
Registration timing: **prospective**

Last update: **2025-01-02, 1403/10/13**
Update count: **0**

Registration date

2025-01-02, 1403/10/13

Registrant information

Name

Sajedeh Bahjati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

sajedeh.bahjati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-03, 1403/11/15

Expected recruitment end date

2026-02-04, 1404/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating The Effect Of Ferula assa-foetida On The Quantity And Quality Of Eggs In Infertile Women With polycystic ovaries

Public title
Investigating The Effect Of Ferula assa-foetida On The Quantity And Quality Of Eggs In Infertile Women With polycystic ovaries

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18 to 40 years2. History of primary or secondary infertility3. Diagnosis of polycystic ovary syndrome based on the opinion of a specialist doctor4. No known mental illness or any illness that affects the fertility process.5. Normal fallopian tubes.6. The absence of infertility in the spouse, according to the doctor's approval. History of primary or secondary infertility Diagnosis of polycystic ovary syndrome based on the opinion of a specialist doctor No known mental illness or any illness that affects the fertility process Normal fallopian tubes The absence of infertility in the spouse, according to the doctor's approval

Exclusion criteria:
The presence of a known mental illness or any illness that may affect the reproductive process. Infertility due to abnormal fallopian tubes Infertility in the spouse The presence of any infertility that has a cause other than polycystic ovary syndrome.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be a double-blind randomized clinical trial with two intervention and control groups. Sampling will be done after completing the informed consent form using the available method and the samples will be selected based on purpose and will be randomly assigned to two groups of intervention (A) and control (B) using quadruple permutation blocks and through lottery, then the intervention will be started with medication for 16 weeks.

Blinding (investigator's opinion)
Double blinded

Blinding description
Coding of drug and placebo packages will be done in the School of Pharmacy of Shahed University of Medical Sciences and by the research consultant, and until the end of data analysis, the researcher and the patient (samples) will be unaware of the method of drug allocation, therefore, this study will be double-blind.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address
Towhid Square, Dr. Mirkhani Street (East Nusrat)

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2025-03-05, 1403/12/15

Ethics committee reference number
IR.TUMS.FNM.REC.1403.153

Health conditions studied

1

Description of health condition studied
Egg quantity and quality in women with polycystic ovary syndrome

ICD-10 code

ICD-10 code description
Egg quantity، Egg quality، Polycystic ovary syndrome

Primary outcomes

1

Description
Egg quantity, which refers to the number of follicles.

Timepoint
16 weeks

Method of measurement
Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention will begin with medication for 16 weeks. The intervention will include the daily intake of two Ovulam capsules, each capsule containing 500 mg of oleogum resin from the plant Ferula assa-foetida.
Category
Treatment - Drugs

2

Description
Control group: The control group will also be prescribed two capsules daily, each capsule being the same size and weight as the Ovalamam capsule and containing bread powder, which will be encapsulated at the Traditional Medicine Clinical Trial Research Center at Shahed University.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina infertility center
Full name of responsible person
Mam Infertility Center
Street address
Ibn Sina Infertility and Recurrent Abortion Treatment Center, Tehran Branch, Shariati Street, Corner of Yakhchal Street, No. 97
City
Tehran
Province
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1983969412
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+98 21 23519
Email
Sajedeh.bahjati@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Ramin kordi
Street address
Towhid Square, Dr. Mirkhani Street (East Nusrat)
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Email
Sajedeh.bahjati@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Sajedeh bahjati
Position
Master's degree student in midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
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Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Because this research is in the form of a thesis, all of the above-mentioned items in this research will be shared in the meetings of the Research Council of the Faculty's Reproductive Health Department and the final defense meeting for the council members.

When the data will become available and for how long

When defending the proposal and final defense of the thesis

To whom data/document is available

Research team members, final report reviewers, and stakeholders (pharmacist and gynecologist)

Under which criteria data/document could be used

In addition to the aforementioned data, possible side effects of the drug can also be provided for the purpose of drug manufacturing.

From where data/document is obtainable

Supervisor Dr. Mehrnaz Garanmayeh Email: geranmay@tums.ac.ir

What processes are involved for a request to access data/document

After the request, if the supervisor and the research team deem it appropriate, the information will be sent according to the contract between them.

Comments