

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the effect of lavender versus metformin on polycystic ovary syndrome

Protocol summary

Study aim

Comparison of the effect of lavender and Metformin on Polycystic ovary syndrome

Design

The Clinical trial will be Open label. Patients will be 68 people. Patients were divided into two random groups: How to randomize Block randomization will be done in the form of 4 blocks.

Settings and conduct

After the diagnostic test was performed And based on ultrasound, polycystic ovaries were confirmed for them According to the randomization table in one of the groups of lavender capsules or metformin tablets After taking the drug for three months, the menstrual pattern of the people is examined and if it becomes regular, Serum progesterone levels in the luteal phase will be measured by referral to a laboratory.

Participants/Inclusion and exclusion criteria

Entry requirements: Diagnosis of Poly cystic ovary syndrome by a Gynecologist Do not take Diabetes medications, Hyper lipidemia medications, or Blood pressure medications No entry conditions: No Pregnancy or Breastfeeding Do not take Insulin sensitizers Do not take Aspirin or other Anticoagulants Do not take Anti-prostaglandin drugs Do not take other Herbal medicines at the same time for your disease No history of uncontrolled blood pressure, stroke, heart attack, cancer, Cardiovascular disease, liver, kidney and thyroid disorders, Diabetes No smoking Do not take Oral Contraceptives

Intervention groups

After taking the drug for three months ,Menstrual patterns are examined and if they are regular Serum progesterone levels will be measured in the luteal phase

Main outcome variables

Measurements of serum progesterone in the luteal phase show more than 3 ng / ml The answer is to cure and prove ovulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210915052488N1**

Registration date: **2021-11-18, 1400/08/27**

Registration timing: **prospective**

Last update: **2021-11-18, 1400/08/27**

Update count: **0**

Registration date

2021-11-18, 1400/08/27

Registrant information

Name

Saeed reza Simaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3844 2398

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of lavender versus metformin on polycystic ovary syndrome

Public title

Effect of lavender in treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of polycystic ovary syndrome by a gynecologist

Exclusion criteria:

Do not take drugs that lower blood pressure, blood fats and blood sugar No pregnancy or breastfeeding Do not take insulin sensitizers Do not take aspirin or other anticoagulants Do not take anti-prostaglandin drugs Do not take other herbal medicines at the same time for your disease No history of uncontrolled blood pressure, stroke, heart attack, cancer or heart attack, cardiovascular disease, liver, kidney and thyroid disorders, type 1 or 2 diabetes No smoking Do not take oral contraceptives

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in block method with 4 blocks. Random sequencing will be generated by the epidemiology and statistics consultant using the site <https://www.sealedenvelope.com>. Randomization unit: individual Hide: Only the consultant will be aware of the random sequence. In the mentioned site, it is possible to assign a code to each person. Therefore, the next person will not know what treatment he is going to receive (A or B) and only the person who performed the random sequence And will not be involved in assigning samples to groups and evaluating patients will be aware of the random sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this Clinical trial is double-blind. The participant and the data evaluator will not know the type of treatment assigned. The shape of the drugs and their box are quite similar and Neither the participant nor the evaluator will know about its content.

Placebo

Not used

Assignment

Parallel

Other design features

Fasting glucose and insulin levels, prolactin, serum basal progesterone and TSH and free testosterone are measured. For patients with a radiologist with a vaginal ultrasound, a polycystic ovary view must be confirmed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

No. 2, Central Building., Kermanshah University of Medical Sciences., Shahid Beheshti Street

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.KUMS.REC.1400.327

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

Check menstrual days

Timepoint

After three months of treatment in the luteal phase

Method of measurement

Day

Secondary outcomes

1

Description

Measurement of serum Progesterone in the luteal phase

Timepoint

After three months of treatment in the luteal phase

Method of measurement

Measurement of serum progesterone in the luteal phase more than 3 Nanogram / milliliter

Intervention groups

1

Description

Intervention group: The drug is in the form of 500 mg capsules(One hundred grams of lavender is boiled in one liter of water to reach 100 milliliter The solution is then passed through a strainer. The filtered solution is poured into a snail to reach a concentration of 100 to 10 gram of dry extract. Capsules are made using 250 mg of starch oxide and 250 milligram of lavender. Product standardization is based on the total phenolic content).It is prescribed twice a day for three months. Made by Engineer Kamalinejad in the laboratory of the Faculty of Pharmacy, hahid Beheshti University of Medical Sciences, Tehran.

Category

Treatment - Drugs

2

Description

Control group: This group is prescribed metformin 500 milligram tablets three times a day for three months.From the pills of Abidi Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Aria Hospital

Full name of responsible person

Mahboubeh Rostami

Street address

West Golestan Ave., Shahid Gamran Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khoda Rahmi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Saeed Reza Simaei

Position

Resident

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study scientific data Except for personal data of individuals will be shared.

When the data will become available and for how long

Scientific content will be available six months after the results are published

To whom data/document is available

Scientific data and documentation will be available to researchers

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Saeed Reza Simaei sreza.simaei@kums.ac.ir

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

After confirming the reference, the file will be sent to the applicant no later than one month later

Comments