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
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Iran (Islamic Republic of)
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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
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West Golestan Ave., Shahid Gamran Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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 updating data

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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