Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Ferula assafoetida on clinical and paraclinical indices of polycystic ovarian syndrome and its comparison with LD tablet.

Protocol summary

Study aim

1- Effect of Ferula assafoetida on: 1-1- Improvement of menstrual status and hirsutism 1-2- Body mass index (BMI) and laboratory tests 1-3- Treatment of ovarian cysts in patients with Polycystic ovarian syndrome 2- It's comparison with Ld tablet.

Design

Two arm parallel group randomized clinical trial, double-blind, with 30 patients.

Settings and conduct

The study will be conducted in Mostafa Khomeini hospital in Tehran. Thirty patients with diagnosis of Polycystic ovarian syndrome will be selected and after doing different tests (CBC, LIPID PROFILE, FBS, AST, ALT,ALK.P, TOTAL TESTESTRONE,FREE TESTESTRONE), ovarian ultrasound, hirsutism examination and filling demographic information questionnaires, will enter the study. Patients meeting the inclusion and exclusion criteria randomly will divide into two groups, using a double-blind design. One group will be treated with Ferula Assafoetida capsules (1gram per day) and other group will be treated with OCP (0.03 mg Ethinyl Estradiol and 0.3 mg Norgestrel or 0.15 mg Levonorgestrel). Patients will be asked to use the drugs for three weeks and discontinue the consumption for one week. Thereafter, patients will use the drugs for an extra three weeks. Finally, they will be evaluated after seven to ten days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 15 to 40 years old women with Polycystic ovarian syndrome. Exclusion criteria: Pregnancy, diabetes, thyroid diseases, allergy to Ferula Assafoetida, differential Diagnosis cases of PCOS

Intervention groups

Case group: Intervention with Ferula assafoetida capsule (1 gr per day) for 6 weeks. Control group: Intervention with ocp (LD tablet: 0.03 mg ethinyl estradiol and 0.3 mg norgestrel or 0.15 mg levonorgestrel) for 6 weeks.

Main outcome variables

Presence of ovarian cysts, occurrence of menstruation bleeding, hirsutism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190728044360N1**
Registration date: **2019-12-11, 1398/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-11, 1398/09/20**
Update count: **0**

Registration date

2019-12-11, 1398/09/20

Registrant information

Name
Najmeh Dehparvar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 25 3770 1938
Email address
n.dehparvar@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Ferula assafoetida on clinical and paraclinical indices of polycystic ovarian syndrome and its comparison with LD tablet.

Public title
Effect of Ferula Assafoetida on polycystic ovarian syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All 15 to 40 years old women with polycystic ovarian syndrome
Exclusion criteria:
Pregnancy Allergy to Ferula Asafoetida Diabetic patients Thyroid diseases
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Method: Simple randomization Unit: Individual Tool: Random numbers table
Blinding (investigator's opinion)
Double blinded
Blinding description
All participants in this project and the clinical caregiver who is responsible for getting medication to the participants and the physician (researcher) who collects the data, are blind to the type of intervention provided to each participant.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee on Biomedical Research of Shahed University
Street address
Shahed University, Persian Gulf Highway (Tehran - Qom), Tehran
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2018-12-24, 1397/10/03
Ethics committee reference number
IR.SHAHED.REC.1397.092

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Presence of ovarian cysts
Timepoint
Before Intervention and seven days after Intervention
Method of measurement
Sonography

2

Description
Occurrence of menstrual bleeding
Timepoint
4 and 8 weeks after the beginning of treatment
Method of measurement
asking

3

Description
Hirsutism
Timepoint
Before Intervention and seven days after Intervention
Method of measurement
Ferriman–Gallwey scale

Secondary outcomes

1

Description
Body mass index

Timepoint
Before Intervention and seven days after Intervention
Method of measurement
Meter and scale

2

Description
Total Testosterone
Timepoint
Before Intervention and seven days after Intervention
Method of measurement
CLIA laboratory method

3

Description
Free Testosterone
Timepoint
Before Intervention and seven days after Intervention
Method of measurement
ELIZA laboratory method

Intervention groups

1

Description
Case group: This group will be treated with Ferual Assafoetida (1 gram daily) for three weeks and discontinue the consumption for one week. Thereafter, patients will use the drugs for an extra three weeks.
Category
Treatment - Drugs

2

Description
Control group: This group will be treated with LD tablet with formulation of 0.03 mg Ethinyl Estradiol and 0.3 mg Norgestrel or 0.15 mg Levonorgestrel for three weeks and discontinue the consumption for one week. Thereafter, patients will use the drugs for an extra three weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mostafa Komeini hospital
Full name of responsible person
DR. Ahia Garshasbi
Street address
Italia Ave., Felestin Ave.
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 8896 6131
Email
Dr.garshasbi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr. Zahra Kiasalari
Street address
Shahed university, Persian Gulf Highway (Tehran - Qom)
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Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 5106
Email
info@shahed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
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
Shahed University
Full name of responsible person
Najmeh Dehparvar
Position
Persian Medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address

No. 26, Alley 2, Razavi Boulevard, Jihad Square, Bajak
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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
The information about the main outcome will shared.
When the data will become available and for how long
The access period begins 6 months after publishing of results.
To whom data/document is available
It will be accessible to everyone.
Under which criteria data/document could be used
For scientific works with observing the principles of research ethics
From where data/document is obtainable
Najme Dehparvar, Mobile number: 00989122530421, Email: dehparvar.mah@gmail.com, Address: No. 26, Alley 2, Razavi Boulevard, Jahad Square, Qom
What processes are involved for a request to access data/document
Upon confirmation of the scientific identity of the Iranian questioner, he or she will be provided as soon as possible.
Comments