

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The effect of Date Palm Pollen on folliculogenesis and liver enzymes in women with polycystic ovary syndrome: a double-blind randomized clinical trial

Protocol summary

Study aim

investigate the effect of Date Palm Pollen on liver enzymes and ovarian volume in women with PCO

Design

This double-blind randomized controlled clinical trial study is conducted in parallel, on patients referred to women's educational clinics in Abadan and Khorramshahr cities. The sample size is considered to be 40 people based on previous studies.

Settings and conduct

training clinics in Abadan and Khorramshahr cities

Participants/Inclusion and exclusion criteria

Women with polycystic ovary syndrome are eligible; People who use tobacco and alcohol or suffer from chronic kidney, liver, lung diseases and chronic or acute inflammatory diseases (especially acute inflammation of the pancreas), thyroid dysfunction, heart valve disease, short bowel syndrome Also, people with low immune system ability (autoimmunity) are removed from the list of eligible people (this condition is approved by the clinical consultant for the studied people), as well as people who are allergic to medicine or placebo during the study and or take chemotherapy drugs (tamoxifen) and corticosteroids, or drugs that affect blood sugar and lipids (insulin injection, statins, diuretics), antibiotics and vitamin supplements and omega-3, or have one of the diseases If the above-mentioned patients were hospitalized or had to change the dosage of the drugs they were taking, they were excluded from the study.

Intervention groups

In this study, people will be divided into two control and intervention groups using a random number table. The first group will be under the standard drug regimen (metformin + spironolactone) for the treatment of PCO along with the daily intake of 400 mg of date palm pollen, and the second group will be under the standard medication regimen for the treatment of PCO along with

the daily intake of 400 mg of the placebo drug (dry bread).

Main outcome variables

Evaluation of biomarkers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230531058351N1**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

samaneh Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5326 7800

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Date Palm Pollen on folliculogenesis and liver enzymes in women with polycystic ovary syndrome: a double-blind randomized clinical trial

Public title
Investigating the effect of Date Palm Pollen on women with polycystic ovary syndrome

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
To diagnose polycystic ovary syndrome according to the Rotterdam criteria, two of the following must be present: 1- Amenorrhea or reduced ovulation frequency Presence of hyperandrogenism based on clinical symptoms (hirsutism and male pattern hair loss) or laboratory (androgen increase) free or increased free androgen index) the presence of evidence of polycystic ovary in ultrasound.

Exclusion criteria:
People who use tobacco and alcohol. People suffering from chronic kidney, liver, lung diseases and chronic or acute inflammatory diseases (especially acute inflammation of the pancreas), thyroid dysfunction, heart valve disease, short bowel syndrome. Also, people with low ability of immune system (autoimmunity) are removed from the list of eligible people. These conditions are approved by the clinical consultant in the case of the studied subjects. Also, people who are allergic to medicine or placebo during the study. or taking chemotherapy drugs (tamoxifen) and corticosteroids, or drugs affecting blood sugar and lipids (insulin injections, statins, diuretics), antibiotics and vitamin supplements and omega 3, or suffering from one of the above-mentioned diseases Either they were admitted to the hospital or they had to change the dosage of the drugs they were taking, they were excluded from the study. To overcome the confounding factors, we use the general information questionnaire and the three-day record of people's food intake.

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Randomization tool: table of random numbers In this study, 80 envelopes will be designed, in which there is code A or code B inside each envelope. These codes will indicate the allocation or non-allocation of the intervention. In advance, the necessary coordination will be made with the pharmaceutical company to make the drug and placebo, and the drug and placebo will be separated in containers with code A and B. According to the double-blind study, neither the doctor nor the patient will be unaware of these containers. The patient goes to the doctor and the doctor will place the person in one of these two groups with the help of a table of random numbers. This will continue until 80 people are placed in two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, people will be divided into two control and intervention groups using a random number table. . Date palm pollen and dry bread powder will be packaged and coded in exactly the same packages, and the researcher and the subject are not aware of the type of supplement consumed in the packages.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committees of Abadan School of Medical Sciences

Street address

Zulfiqari St, Abadan University of Medical Sciences

City

Abadan

Province

Khuzestan

Postal code

6319811154

Approval date

2022-09-13, 1401/06/22

Ethics committee reference number

IR.ABADANUMS.REC.1401.068

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

Alanine Aminotransferase(ALT)

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week

Method of measurement

VT3000 device will be used to measure liver enzymes.

2

Description

Aspartate Aminotransferase(AST)

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week

Method of measurement

VT3000 device will be used to measure liver enzymes.

3

Description

Alkaline Phosphatase(ALK-P)

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week.

Method of measurement

VT3000 device will be used to measure liver enzymes.

4

Description

17 α hydroxy-progesterone

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week.

Method of measurement

LC/MS/MS device is used to measure steroid hormones.

5

Description

Progesterone

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week.

Method of measurement

LC/MS/MS device is used to measure steroid hormones.

6

Description

androstenedione

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week.

Method of measurement

LC/MS/MS device is used to measure steroid hormones.

7

Description

estrogen

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week.

Method of measurement

LC/MS/MS device is used to measure steroid hormones.

8

Description

LH

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week.

Method of measurement

LC/MS/MS device is used to measure steroid hormones.

9

Description

CBC

Timepoint

Measurement of biomarkers at the beginning of the study and after the twelfth week.

Method of measurement

Blood tests are performed by means of TB counter machines.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: participants in the intervention group received 400 mg Date Palm Pollen once a day after lunch for 12 weeks. After characterizing Date Palm Pollen native to Abadan city, Karen Pharmaceutical Company prepares the product in the form of capsules, Pearl 400 mg. The subjects and the researcher do not know about the allocation of groups. In order to hide the assignment of people to groups, sealed envelopes are used (containing the identification group code of each person along with inserting the person's number on the envelope). A time table is designed to take the medicine. Drug intake was assessed by counting the remaining pearls and by excluding participants who did not consume more than 30% of the drug.

Category

Treatment - Drugs

2

Description

Control group: Participants in the control group received

placebo Pearl (dry bread) 400 mg once a day after lunch for 12 weeks. In terms of appearance, placebos are completely similar to date palm pollen herbal medicine, both of which are produced by Karen Pharmaceuticals and Vital Food Supplements Company (Yazd-Tehran). The investigated people and the researcher do not know about the allocation of groups. Placebo and date palm pollen herbal medicine are coded by the manufacturing company. In order to hide the assignment of people to groups, sealed envelopes are used (containing the assigned group code of each person along with the individual's number on the envelope). A schedule is designed to remind you to take the medicine. The evaluation of drug consumption is done by counting the remaining pearls and by removing the participants who have not consumed more than 30% of the drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's educational clinics in Abadan and Khorramshahr cities

Full name of responsible person

Samaneh Karimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Educational and Research Vice-Chancellor of Abadan University of Medical Sciences

Full name of responsible person

Nabi Jome zadeh

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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

Educational and Research Vice-Chancellor of Abadan 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

Abadan University of Medical Sciences

Full name of responsible person

Samaneh Karimi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Published as an article

When the data will become available and for how long

After publication as an article

To whom data/document is available

After publication as an article

Under which criteria data/document could be used

Published as an article

From where data/document is obtainable

Author

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

Published as an article

Comments