

# 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

##### Email address

samaneh\_k\_500@yahoo.com

##### 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 $\alpha$  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

##### Street address

Zulfiqari St, Abadan University of Medical Sciences

##### City

Abadan

##### Province

Khuzestan

##### Postal code

6319811154

##### Phone

+98 61 5326 7800

##### Email

samaneh\_k\_500@yahoo.com

## 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

##### Street address

Zulfiqari St, Abadan University of Medical Sciences

##### City

Abadan

##### Province

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##### Postal code

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##### Phone

+98 61 5326 7800

#### Email

samaneh\_k\_500@yahoo.com

#### 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

#### 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 updating data****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**

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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**