

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical trial comparison of the effect of capsule of date palm pollen with clomiphene citrate compared with clomiphene citrate only, on the levels of hormones in clomiphene citrate resistant infertile women with polycystic ovary syndrome

Protocol summary

Summary

Goal: Evaluation of the effect of capsule of date palm pollen in infertile women with polycystic ovary syndrome.
Method: Randomly choose two groups including 50 women each, from day 5 to end of the cycle. First group use clomiphene citrate with date palm pollen capsules. second group use placebo with clomiphene citrate. Level of fertility hormones will be checked before and during interventional on days 3 and 21 of cycle. Primary outcome measure: Measurement of fertility hormones including gonadotropins(LH, FSH and their ratio), testosterone, progesterone and prolactin on days 3 and 21 of menstrual cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082016911N4**

Registration date: **2017-11-03, 1396/08/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-03, 1396/08/12

Registrant information

Name

Bahar Morshed Behbahani

Name of organization / entity

Shiraz Medical University

Country

Iran (Islamic Republic of)

Phone

+98 71 1630 1288

Email address

morshed_b@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparison of the effect of capsule of date palm pollen with clomiphene citrate compared with clomiphene citrate only, on the levels of hormones in clomiphene citrate resistant infertile women with polycystic ovary syndrome

Public title

Evaluation of the effect of capsule of date palm pollen in infertile women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Clomiphene Citrate resistant infertile women with polycystic ovary syndrome
Exclusion criteria: Having no desire to cooperate; Having allergy to date palm pollen; Interrupt treatment in ovulation period; Not using Clomiphene or date palm pollen capsule;

allergic to date palm pollen; having chronic disease(Heart, respiratory, kidney and digestive diseases); using other herbal drugs that affect infertility

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization with Blocked Randomization Method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand st.

City

Shiraz

Postal code

713451978

Approval date

2016-10-09, 1395/07/18

Ethics committee reference number

IR.SUMS.REC.1395.119

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

2

Description of health condition studied

Infertility due to PCO

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Prolactine

Timepoint

Before and During intervention in Days 3 and 21 of cycle

Method of measurement

Blood Sample

2

Description

Progesterone

Timepoint

Before and During intervention in Days 3 and 21 of cycle

Method of measurement

Blood Sample

3

Description

Gonadotropines

Timepoint

Before and During intervention in Days 3 and 21 of cycle

Method of measurement

Blood Sample

4

Description

Testestrone

Timepoint

Before and During intervention in Days 3 and 21 of cycle

Method of measurement

Blood Sample

Secondary outcomes

empty

Intervention groups

1

Description

Date Palm pollen capsule, 2 grams daily from day 5 to end of the cycle and Clomiphene citrate, 150 ml grams daily from day 5 to 9 of the menstrual cycle.

Category

Treatment - Drugs

2

Description

Placebo 2 grams daily, from day 5 to the end of the cycle and Clomiphene citrate, 150 ml grams daily from day 5 to 9 of the menstrual cycle.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir mother and child hospital

Full name of responsible person

Maryam Alsadat Hadigheh

Street address

Golshan City, Quran gate, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Maryam Alsadat Hadigheh

Street address

Zand Street

City

Shiraz

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Alsadat Hadigheh

Position

Midwife

Other areas of specialty/work

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Namazi Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Bahar Morshed Behbahani

Position

Masters

Other areas of specialty/work

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Email

morshed_b@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Nursing and Midwifery Collage

Full name of responsible person

Maryam Alsadat Hadigheh

Position

midwife

Other areas of specialty/work

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>