

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

To evaluate the effect of a Persian medicine product, containing silk, on the incidence of pregnancy in infertile women with polycystic ovary syndrome-A Randomized clinical trial

Protocol summary

Study aim

Determining the effect of "Iranian medicinal product made from silk" on the occurrence of pregnancy in infertile women with polycystic ovary syndrome.

Design

A randomized clinical trial with a control group, with parallel groups, and thruple blind with 58 samples, the Rand function of Excel software, was used for randomization.

Settings and conduct

Infertile patients referred to Reihaneh Qom Infertility Center who meet the entry criteria of the study are selected by the researcher, then the details of the study will be explained by the researcher. Then the patients are randomly assigned to one of the two treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult women, aged between 20 and 40, infertile women with polycystic ovary syndrome, infertility for at least 1 year, and a maximum of 5 years. Exclusion criteria: infertility due to male factor, infertility due to tubal causes, endometriosis, patients with liver, kidney, joint, rheumatic, and metabolic disorders

Intervention groups

Intervention group: In addition to receiving letrozole (5 mg) daily from the third to the seventh day of the menstrual cycle, the intervention group will be treated with an Iranian medicine product made from silk 3 times a day, 10 cc each time the morning and evening during 3 cycles of ovulation stimulation from days first to 14. It will be from the first to the fourteenth of the menstrual cycle. Control group: In addition to receiving letrozole (5 mg) daily from the third to the seventh day of the menstrual cycle, they will be treated with placebo syrup 10 cc 3 times a day during 3 ovulation stimulation cycles from the first to the fourteenth day of the menstrual cycle.

Main outcome variables

Ovarian follicle size, dominant follicle number, endometrial thickness and pattern, chemical fertility rate, clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221009056122N1**

Registration date: **2022-11-01, 1401/08/10**

Registration timing: **prospective**

Last update: **2022-11-01, 1401/08/10**

Update count: **0**

Registration date

2022-11-01, 1401/08/10

Registrant information

Name

Batoul Khayatzaheh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To evaluate the effect of a Persian medicine product, containing silk, on the incidence of pregnancy in infertile women with polycystic ovary syndrome-A Randomized clinical trial

Public title
To evaluate the effect of a Persian medicine product, containing silk, on the incidence of pregnancy in infertile women with polycystic ovary syndrom

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Infertile women suffering from polycystic ovary syndrome referred to Rehan Infertility Center, Nekou Hospital, Qom. Informed consent to enter the plan The period of infertility is at least 1 year and at most 5 years BMI less than 30 kg/m2
Exclusion criteria:
 Male factor Infertility Tubular infertility other types of ovarian cysts except for PCO Endometriosis Premature ovarian failure (POF) and decreased ovarian reserve (DOR) Underlying and systemic disease and malignancy Breast diseases such as breast cysts Liver, kidney, joint and rheumatic disorders Other diseases including metabolic diseases such as diabetes and endocrine disorders including uncontrolled hypothyroidism, hyperprolactinemia, and Cushing's disease Breast diseases such as breast cysts Liver, kidney, joint and rheumatic disorders Other diseases including metabolic diseases such as diabetes and endocrine disorders including uncontrolled hypothyroidism, hyperprolactinemia, and Cushing's disease Other diseases include metabolic diseases such as diabetes and endocrine disorders including uncontrolled hypothyroidism, hyperprolactinemia, and Cushing's disease

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description
 Allocations will be made by simple randomization of patients available at the infertility treatment center. In the first step, the groups are written in the form of groups A and B. Then, to assign the intervention group and the control group to group A or B, a lottery is drawn between the two groups. In the second step, numbers from 1 to 58 are written on paper so that they are not visible and thrown into a container. In the third stage, a person announces that patients choose the intervention or control group, then picks up a number from the container and reads it and writes notes in the group he or she announced. This is repeated 29 times without replacement; To identify all the people belonging to the announced group. The remaining 29 numbers are then assigned to the second group. Finally, at the time of each patient's visit to the infertility center, each patient selects a number from a container containing 58 numbers from 1 to 50 and gives it to the researcher, then the researcher selects the patient in the relevant group according to the selected number. This is done up to 58 times to complete the groups

Blinding (investigator's opinion)
Triple blinded

Blinding description
 The present study is a three-blind study. In this study, the patient, the facilitator (physician) and the statistical consultant will not know the content of the syrup and blinding will be done for them. Only the traditional medicine referee who is responsible for preparing the syrup of Iranian traditional medicine and placebo syrup will know the content of medicinal syrups. Individuals who have the inclusion criteria, if they wish to participate in the study, after obtaining informed written consent, take the syrup of traditional Iranian medicine and placebo, which are in the same package and completely similar in terms of color and aroma randomly. The blinding method will be performed in such a way that a special code will be considered for each syrup and it will be recorded on the syrup label. Only pharmacist consultant will know about drug codes. Medications will be provided to the physician, project manager, and patient. The code of each syrup for each patient will be inserted in the file and the patient checklist by the executor. At the end of the study, for statistical analysis, information and patient checklist form will be provided to the statistical consultant, and after analyzing the data, the syrup code will be provided to the executor and statistical consultant by the pharmacist for final analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Qom University of Medical Sciences

Street address

No. 83, Shahid Lotfi Niasar (Alley No. 4), University Jihad Alley, Saffashahr St.

City

Qom

Province

Ghous

Postal code

9345637169

Approval date

2022-07-04, 1401/04/13

Ethics committee reference number

IR.MUQ.REC.1401.092

Health conditions studied

1

Description of health condition studied

Infertility in women with polycystic ovary syndrome

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

After the first delay in menstruation, the fourth week of the menstruation cycle

Method of measurement

Serum B-hCG measurement

Secondary outcomes

1

Description

clinical pregnancy

Timepoint

After a positive serum B-hCG test, the fifth to sixth week of the menstruation cycle

Method of measurement

Observing fetal heart rate on ultrasound

2

Description

The level of anxiety

Timepoint

The beginning and end of the intervention

Method of measurement

Anxiety score in Beck's questionnaire

Intervention groups

1

Description

Intervention group: the intervention group, in addition to the common ovulation-stimulating drug, letrozole 2.5 mg twice (5 mg) once a day from the third to the seventh day of the menstrual cycle (and if necessary HMG and Sinal F), silk worm cocoon syrup made by Qom School of Traditional Medicine during 3 ovulation stimulation cycles from the first to the fourteenth menstrual cycle will be given three times a day, 10 cc each morning and evening.

Category

Treatment - Drugs

2

Description

Control group: the control group, in addition to the common ovulation-stimulating drug, letrozole 2.5 mg twice (5 mg) once a day from the third to the seventh day of the menstrual cycle (and if necessary HMG and Sinal F), placebo syrup made by Qom School of Traditional Medicine during 3 ovulation stimulation cycles from the first to the fourteenth menstrual cycle will be given three times a day, 100 cc each morning and evening.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Reihaneh Infertility Center, Nakoi Hospital, Qom

Full name of responsible person

Dr. Howra Amouzgar, specialist in obstetrics and gynecology - infertility and IVF fellowship

Street address

Taleghani Street (Azer) - next to Mirzai Qomi Square - Nekoui Hedayati Farghani Educational and Therapeutic Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Alireza Koohpaye

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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

Ghoum 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**

Ghoum University of Medical Sciences

Full name of responsible person

Batoul Khayatzaheh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

Majid asghari

Position

lecturer

Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

make this available

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

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

Data Dictionary

Not applicable