Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 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 thriple 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
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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 Rehane Infertility Center, Nekoui 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
Ghoum

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 meausurment

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 coccon 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

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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
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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 Khayatzadeh

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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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