Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

The effect of Persian medicine product containing asparagus root (Asparagus officinalis L) on ovarian follicle growth and incidence of pregnancy in infertile women with polycystic ovarian syndrome (PCOS)

Protocol summary

Study aim
Determining the effect of Iranian medicine product containing asparagus root on ovarian follicle growth and pregnancy in infertile women with polycystic ovarian syndrome (PCOS)

Design
Random and controlled clinical trial, three-blind with 50 samples

Settings and conduct
Infertile patients referred to the infertility center of Shahid Beheshti Hospital in Kashan who have the inclusion criteria of the study will be selected by the researcher, then the details of the study will be explained by him, then a questionnaire including demographic characteristics and disease information will be prepared. Patients are then randomly assigned to one of two treatment groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult women, aged between 20 to 35, infertile women with polycystic ovarian syndrome, infertility of at least 1 year and up to 5 years / Exclusion criteria: Male factor infertility , infertility due to tubular cause, endometriosis, patients with liver, kidney, joint and rheumatic and metabolic disorders

Intervention groups
Intervention: 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 Iranian medicine product containing asparagus root syrup twice a day, 30 cc each morning and evening during 2 ovulation stimulation cycles from the first to the fourteenth day of the menstrual cycle. Control: In addition to receiving letrozole (5 mg) daily from the third to the seventh day of the menstrual cycle, the control group will be treated with 30 cc placebo syrup in the morning and evening during 2 ovulation stimulation cycles from the first to the fourteenth day of the menstrual cycle.

Main outcome variables
Ovarian follicle size, numbers of dominant follicles, endometrial thickness and pattern, chemical fertility rate, clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211214053410N1**
Registration date: **2021-12-27, 1400/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-27, 1400/10/06**
Update count: **0**

Registration date
2021-12-27, 1400/10/06

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Persian medicine product containing asparagus root (Asparagus officinalis L) on ovarian follicle growth and incidence of pregnancy in infertile women with polycystic ovarian syndrome (PCOS)

Public title
The effect of asparagus root on fertility in infertile women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women with polycystic ovarian syndrome (PCOS) based on the Rotterdam Criteria 20 to 35 years old Informed consent to participate in the study Minimum and maximum Infertility period: 1-5 year BMI less than 30 kg per square meter
Exclusion criteria:
Male factor Infertility Tubular infertility other types of ovarian cysts except PCO Endometriosis Premature ovarian failure (POF) and decreased ovarian reserve (DOR) Underlying and systemic disease and malignancy Breast disease 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 Taking herbal medicine during the last month Lack of cooperation to continue the study Severe allergy or drug complications Risk of Ovarian Ovulation Syndrome (OHSS) The entering The patient into a new treatment phase during the study
Age
From **20 years** old to **35 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: **50**
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 50 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 25 times without replacement; To identify all the people belonging to the announced group. The remaining 25 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 50 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 50 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.
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Ghoum
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Approval date
2021-11-30, 1400/09/09

Ethics committee reference number
IR.MUQ.REC.1400.182

Health conditions studied

1

Description of health condition studied
infertility

ICD-10 code
N97.0

ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Ovarian follicle size

Timepoint
Before the intervention and during 10th to 12th of menstrual cycle (in case of lack of proper size of the ultrasound follicle on days 14-16 and finally 20-22 cycles) the first and second months after the intervention

Method of measurement
vaginal ultrasound

Secondary outcomes

1

Description
Numbers of dominant follicles

Timepoint
Before the intervention and during 10th to 12th of menstrual cycle (in case of lack of proper size of the ultrasound follicle on days 14-16 and finally 20-22 cycles)of the first and second month after the intervention

Method of measurement
vaginal ultrasound

2

Description
Endometrial thickness

Timepoint
Before the intervention and during 10th to 12th of menstrual cycle of the first and second month after the intervention

Method of measurement
vaginal ultrasound

3

Description
Endometrial pattern

Timepoint
Before the intervention and during 10th to 12th of menstrual cycle of the first and second month after the intervention

Method of measurement
vaginal ultrasound

4

Description
Chemical pregnancy

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

Method of measurement
Serum B-hCG meausurment

5

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

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), Asparagus root ginger syrup made by Qom School of Traditional Medicine during 2 ovulation stimulation cycles from the first to the fourteenth menstrual cycle will be given twice a day, 30 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 2 ovulation stimulation cycles from the first to the fourteenth menstrual cycle will be given twice a day, 30 cc each morning and evening.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Infertility Center of Shahid Beheshti Hospital, Kashan

Full name of responsible person
Dr. Fatemeh Foroozanfard, Obstetrician and Gynecologist, Infertility and IVF Fellowship

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Position
PhD Student of Traditional Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data will be sent to researchers upon request.

When the data will become available and for how long
After publication the results of study

To whom data/document is available
Researchers

Under which criteria data/document could be used
for systematic or meta-analysis study

From where data/document is obtainable
Dr Fatemeh Nojavan

What processes are involved for a request to access data/document
E-mail correspondence with the principle researcher

Comments