# 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**


**Name**
Mina Atharizadeh

**Name of organization / entity**

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Iran (Islamic Republic of)

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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.
**City**
Qom
**Province**
Ghoum
**Postal code**
9345637169

**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

**Street address**
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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**
Mina Atharizadeh

**Position**
PhD Student of Traditional Medicine

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Traditional Medicine

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## Person responsible for scientific inquiries

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**Latest degree**
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## Person responsible for updating data

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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**