Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Vitagnus tablets on follicle number and size, endometrial thickness and fertility in infertile women with polycystic ovary syndrome

Protocol summary

Study aim
To determine the effect of Vitagnus pill on follicle number and size, endometrial thickness and fertility in infertile women with polycystic ovary syndrome

Design
Clinical trial with control group, three-way blind, randomized, with 60 patients

Settings and conduct
The present study was performed on 60 women aged 18 to 35 years who referred to the office of a gynecologist in Shiraz. These people will be included in the study if they meet the inclusion criteria. The results of the intervention will be evaluated by ultrasound. This study is a three-way blind and will be performed by a person unrelated to the sample allocation study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 35 years, infertility known due to polycystic ovary syndrome, lack of other androgenic disorders, lack of diseases such as: hypothyroidism or hyperthyroidism, hyperprolactinemia, kidney disease, heart disease, etc., Non-use of infertility drugs in the last three months, body mass index 18 to 35, lack of food and drug allergies. Exclusion criteria: breastfeeding, smoking and drug use, stressful event in the last three months, previous surgery on one or both ovaries, taking haloperidol

Intervention groups
Control group: First month: 1 mg of folic acid daily and one empty capsule as a placebo and the second month: In addition to the first month drugs, from the fifth to the ninth day, two letrozole. Intervention group: First month: 1 mg of folic acid daily and one capsule containing two Vitagnus tablets and the second month: In addition to the first month drugs, from the fifth to the ninth day, two letrozole tablets per night

Main outcome variables
Number and size of follicles, endometrial thickness, fertility rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200831048569N1**
Registration date: **2020-10-29, 1399/08/08**
Registration timing: **prospective**

Last update: **2020-10-29, 1399/08/08**
Update count: **0**

Registration date
2020-10-29, 1399/08/08

Registrant information

Name
Vahideh Behmard
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3731 7895
Email address
behmard.v@gmail.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-07-21, 1400/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Vitagnus tablets on follicle number and size, endometrial thickness and fertility in infertile women with polycystic ovary syndrome

Public title
The effect of Vitagnos tablets on the function of polycystic ovaries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 35 years Having written consent to participate in the study Infertility is known to cause polycystic ovary syndrome and rule out other causes of infertility Ultrasound-confirmed polycystic ovaries along with another Rotterdam criteria No other androgenic disorders such as adrenal hyperplasia or androgen-producing tumor Manifestations of hyperandrogenism (high testosterone) No diseases such as: hypothyroidism or hyperthyroidism, hyperprolactinemia, kidney, heart, liver, bone diseases, pituitary tumor, cancer and diabetes Do not take infertility drugs or any other hormonal drugs in the last three months Body mass index 18 to 35 Hypersensitivity to food and drugs such as lactose, letrozole and vitagnus
Exclusion criteria:
Breastfeeding Smoking and drugse Stressful events in the last three months Previous surgery on one or both ovaries Taking haloperidol
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
For sampling, first each of the eligible individuals is selected to enter the study and then the samples will be placed in each of the two groups (intervention) A or (control) B according to the available method based on quadruple block and random allocation. 4 blocks will be used for sampling (AABB, ABAB, BBAA, BABA, ABBA, BAAB).
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, each questionnaire and medication package will be identified by the letters A (intervention group) and B (control group). The researcher, clinical caregiver (gynecologist) and the data analyst are blind to the type of intervention provided to each participant so that they do not know which questionnaire and medication package belong to which group. The only informed person is the midwife working at the sampling site. This person is fixed until the end of the study and his only role in the study is randomization. After explaining the research to the research units and obtaining informed written consent based on random allocation, they will be placed in two groups of intervention and control. 4 blocks will be used for sampling (AABB, ABAB, BBAA, BABA, ABBA, BAAB).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences
Street address
Asian roadside
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2020-10-20, 1399/07/29
Ethics committee reference number
IR.GMU.REC.1399.083

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Number of follicles
Timepoint
Before the intervention and 1/5 month after the intervention
Method of measurement

Sonography

2

Description
Follicle size
Timepoint
Before the intervention and 1/5 month after the intervention
Method of measurement
Sonography

3

Description
Endometrial thickness
Timepoint
Before the intervention and 1/5 month after the intervention
Method of measurement
Sonography

4

Description
Fertility rate
Timepoint
Before intervention and 2 months after intervention
Method of measurement
BHCG test

Secondary outcomes

1

Description
Improve ovarian function
Timepoint
After the intervention
Method of measurement
sonography

2

Description
side effects
Timepoint
During and after the intervention
Method of measurement
check list

Intervention groups

1

Description
Intervention group: Control group: From the beginning of the monthly cycle, they take 1 mg of folic acid tablets and one empty capsule (placebo) daily. The use of this pill and placebo will continue for two months, ie until the end of the next cycle. In the second menstrual cycle, the standard 2.5 mg letrozole drug is used daily for 5 to 5 nights from the 5th menstrual period.
Category
Placebo

2

Description
Intervention group: Intervention group: Two Vitagnos tablets produced by Dineh Pharmaceutical Company (each tablet containing 20 mg of Vitagnos plant extract) in a capsule for two months from the first day of the menstrual cycle will be taken daily. This pill is available in all pharmacies and is licensed by the Food and Drug Administration. Simultaneously with the use of Vitagnos, 1 mg of folic acid will also be used by members of this group. Also, in this group, from the fifth day of the second cycle, like the control group, they will receive the standard treatment of letrozole for five nights.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Maryam Pishvaee's office
Full name of responsible person
Vahideh Behmard
Street address
22 Street., Shahid Deljoo Ave., Abu Nasr Blvd
City
Shiraz
Province
Fars
Postal code
7147681564
Phone
+98 71 3731 7895
Email
vahideh.behmard@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Shahla Khosravan
Street address
Asian roadside
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028

Fax
+98 51 5722 0578
Email
khosravan@gmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Vahideh Behmard
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
22 Street., Shahid Deljoo Ave., Abu Nasr Blvd
City
Shiraz
Province
Fars
Postal code
7147681564
Phone
+98 71 3731 7895
Email
vahideh.behmard@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Roghaieh Rahmany Bilandi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Asian roadside
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Email
roghaiehrahmany@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Vahideh Behmard
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
No. 7147681564, 22 street, Deljoo Ave, Abu Nasr Blvd
City
Shiraz
Province
Fars
Postal code
7147681564
Phone
+98 71 3731 7895
Fax
Email
vahideh.behmard@gmail.com

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