Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Vitex agnus_castus plant on some marker of oxidative stress, lipid profile and insulin resistance in women with polycystic ovary syndrome: A randomized double blind clinical trial study

Protocol summary

Study aim

The effect of Vitex agnus_castus plant on some marker of oxidative stress, lipid profile and insulin resistance in women with polycystic ovary syndrome: A randomized double blind clinical trial study

Design

This double-blind clinical trial study, which has two control and intervention groups, includes 60 women with polycystic ovary syndrome that using a random allocation method with blocks of four, 30 people will allocate in the control group and 30 people in the drug group.

Settings and conduct

The purpose of the study and how to do it will be explained to patients and written consent will be obtained from them to participate in the study in Taleghani hospital, Arak. Blood samples are taken from patients at the beginning of the study(Sampling is done in the clinic)and factors such as blood fat and etc. are measured in the blood(measurement is done in the Arak university of medical sciences laboratory).Then, the herbal medicine will be used in the participants for 12 weeks, and after this period, blood samples will be taken again and the factors will be measured again in order to evaluate the effect of the medicine. Patients and specialist will not be aware of the type of groups

Participants/Inclusion and exclusion criteria

women in the age range of 18-45 years; whose PCOS has been confirmed by a specialist based on Rotterdam criteria; Only patients who do not intend to become pregnant are allowed to enter our study. The exclusion criteria are thyroid disorders; hyperprolactinemia; diabetes; use of dopamine antagonists and antioxidant supplements.

Intervention groups

A group of Agnugel tablets(a coated tablet containing the dry extract of the Vitex agnus_castus plant with a dose of 5.35 mg per day)and the second group of placebo tablet, similar to Agnugol.

Main outcome variables

Markers of oxidative stress and inflammation

General information

Reason for update

Adding a new ethics committee reference number for the research plan defined on this clinical trial and adding the factors measured in this plan (TNF-α, IL-6 and AMH). Additional clarification and rectification of these items: Inclusion criteria (adding Rotterdam criteria), blinding method description, timepoint of measurement, and also measurement method of the variable "menstrual frequency".

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057493N1**
Registration date: **2023-03-28, 1402/01/08**
Registration timing: **prospective**

Last update: **2025-02-15, 1403/11/27**
Update count: **3**

Registration date

2023-03-28, 1402/01/08

Registrant information

Name
Aniseh Hatami
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 66 4230 7793
Email address
a.hatami@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-04-03, 1402/01/14

Expected recruitment end date
2024-04-02, 1403/01/14

Actual recruitment start date
2023-04-04, 1402/01/15

Actual recruitment end date
2024-01-20, 1402/10/30

Trial completion date
empty

Scientific title
The effect of Vitex agnus_castus plant on some marker of oxidative stress, lipid profile and insulin resistance in women with polycystic ovary syndrome: A randomized double blind clinical trial study

Public title
The effect of Vitex agnus_castus plant in women with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women in the age range of 18-45 years Confirmation of PCOS by a specialist doctor, based on Rotterdam criteria Patient satisfaction to enter the study Patients who do not intend to become pregnant because the profile of therapeutic drugs for people who intend to become pregnant is different from those who do not intend to become pregnant

Exclusion criteria:
Smoking Thyroid disorders Hyperprolactinemia Diabetes Pregnancy Consumption of dopamine antagonists Consumption of antioxidant supplements Breastfeeding

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation method will be used and the patients are placed in the intervention or control group using the block random allocation method with blocks of four. By assigning the letter A to the intervention group and the letter B to the control group, six states AABB, BBAA, BABA, ABBA, BAAB, and ABAB are written on separate sheets and are thrown into a container, and each time one of the sheets is taken out and it's written composition is noted and the sheet is thrown into the container again. Since the sample size in this study is 60, this procedure is repeated 15 times and each time the combination written on each sheet is noted in the sequence of the previous sheet. Then, a number from one to sixty is assigned to each of the letters in the order of the letters noted one after the other, and each of the letters are placed in an envelope and the specific number of each letter is written on the envelope. Every time which a subject is selected, one of the envelopes is opened. According to the number written on the envelope, the patient is introduced into the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and healthcare providers are blinded. The drug and placebo are packaged in similar packages. The treatment group and placebo group will not be aware of the type of intervention they receive.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2023-02-12, 1401/11/23

Ethics committee reference number
IR.ARAKMU.REC.1401.333

2

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Basij square, Sardasht, Arak

City
Arak

Province
Markazi
Postal code
3848176941
Approval date
2024-05-19, 1403/02/30
Ethics committee reference number
IR.ARAKMU.REC.1403.061

3

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2024-10-06, 1403/07/15
Ethics committee reference number
IR.ARAKMU.REC.1403.225

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
Total antioxidant capacity
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

2

Description
Total oxidant status
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

3

Description
Oxidative stress index
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula

4

Description
Malondialdehyde
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

5

Description
High density lipoprotein (HDL-C)
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Spectrophotometry

6

Description
Low-density lipoprotein(LDL-C)
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

7

Description
Triglyceride
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

8

Description
Fasting glucose
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

9

Description
Catalase
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

10

Description
Insulin resistance
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
HOMA-IR model evaluation

11

Description
Reduced Glutathione
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

12

Description
Glutathione peroxidase
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

13

Description
Total Thiol
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

14

Description
Aspartate aminotransferase(AST)
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

15

Description
Alanine aminotransferase(ALT)
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

16

Description
Number of periods
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
To ask the patient and dividing the total number of menstruations that occurred in three months by the expected number of menstruations (three times in three months).

17

Description
The rate of hirsutism
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Ferriman_gallway score

18

Description
Insulin
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
ELISA

19

Description
Cholesterol
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

20

Description
Ovary volume
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Ultrasonography

21

Description
Tumor necrosis factor alpha (measuring on 40 patients)
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
ELISA

22

Description
Interleukin-6 (measuring on 40 patients)
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
ELISA

23

Description
Anti-Mullein Hormone (measuring on 40 patients)
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
ELISA

24

Description
C-reactive protein
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
ELISA

25

Description
The ratio of C-reactive protein to albumin
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula (C-reactive protein / albumin)

26

Description
The ratio of blood urea nitrogen to albumin
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula (blood urea nitrogen / albumin)

27

Description
Albumin bilirubin score
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula (Albumin × -0.085) + (log10 Bilirubin × 0.66)

28

Description
Triglyceride-Glucose index
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula (Fasting triacylglycerols × Fasting glucose/2)

Secondary outcomes

1

Description
Body mass index (BMI)
Timepoint
Before and after 12 weeks of intervention
Method of measurement
Weight /(height)^2

Intervention groups

1

Description
Intervention group: Agnugol tablet (a coated tablet containing the dry extract of the Vitex agnus_castus plant in the amount of 2.3-8.4 mg and an average of 5.35 mg, standardized to 0.42-0.82 mg Aucubin) once a day for 12 weeks(Gol Daro Pharmaceutical Company-Iran-Isfahan Province).
Category
Treatment - Drugs

2

Description
Control group: placebo tablet similar to Agnugol,1 pill per day for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Aniseh Hatami
Street address
Imam Khomeini Street, Shora Square, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3277 4001
Email
Aniseh.Hatami@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mehdi Salehi
Street address
Arak University of Medical Sciences, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3645
Fax
Email
pajoohesh@arakmu.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Aniseh Hatami
Position
Master Student
Latest degree
Master
Other areas of specialty/work
Biochemistry
Street address
Department of Biochemistry, School of Medicine, Arak University of Medical Sciences, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3645
Email
Aniseh.hatami@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Aniseh Hatami
Position
Master Student
Latest degree
Master
Other areas of specialty/work
Biochemistry
Street address
Department of Biochemistry, School of Medicine, Arak University of Medical Sciences, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3501
Email
Aniseh.hatami@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Aniseh Hatami
Position
Master Student
Latest degree
Master
Other areas of specialty/work
Biochemistry
Street address
Department of Biochemistry, School of Medicine, Arak University of Medical Sciences, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3501
Email
Aniseh.hatami@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only results of main outcomes
When the data will become available and for how long
Six months after publishing of the results
To whom data/document is available

Only for academic staffs and universities researches

Under which criteria data/document could be used

Only for international and between universities researches

From where data/document is obtainable

Farideh Jalali-Mashayekhi mashayekhif@yahoo.com

What processes are involved for a request to access data/document

1. Requesting a team work clinical trial via email. 2. Approving the proposal. 3. Registration of the trial

Comments

No comments