Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation the effects of Arctium Lappa root powder on some markers of oxidative stress and inflammation in women with polycystic ovary syndrome: a randomized double blind clinical trial study

Protocol summary

Study aim

Effects of Arctium Lappa root on serum levels of some biochemical variables in women with polycystic ovary syndrome

Design

In this randomized, double-blind, phase 2 study, a total number of 60 people with polycystic ovary syndrome will be selected. They will be divided into two groups of Arctium Lappa root and placebo by block randomization method. They will be matched in age and BMI.

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 because the profile of therapeutic drugs of them is different from those who intend to become pregnant.The exclusion criteria are:consumption anticoagulant drugs and antioxidant and anti-inflammatory supplements 3 months before the study; suffering from diabetes;thyroid disorders;and hyperprolactinemia.

Intervention groups

Recipient group of Arctium Lappa root(One 460 mg capsule per day)and recipient group contains starch with the same dose.

Main outcome variables

Markers of oxidative stress and inflammation

General information

Reason for update

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: **IRCT20230222057492N1**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **prospective**

Last update: **2025-02-09, 1403/11/21**
Update count: **4**

Registration date

2023-03-29, 1402/01/09

Registrant information

Name

Hanieh Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3383 8278

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15
Expected recruitment end date
2024-04-03, 1403/01/15
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
Investigation the effects of Arctium Lappa root powder on some markers of oxidative stress and inflammation in women with polycystic ovary syndrome: a randomized double blind clinical trial study

Public title
Investigation the effects of Arctium Lappa root powder 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 consumption of anticoagulant drugs and antioxidant and anti-inflammatory supplements for 3 months before the study. Pregnancy Breastfeeding Diabetes Thyroid disorders Hyperprolactinemia
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
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Province
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3848176941
Approval date
2023-02-12, 1401/11/23
Ethics committee reference number
IR.ARAKMU.REC.1401.334

2

Ethics committee
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Approval date
2024-05-19, 1403/02/30
Ethics committee reference number
IR.ARAKMU.REC.1403.060

3

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Approval date
2024-10-06, 1403/07/15
Ethics committee reference number
IR.ARAKMU.REC.1403.224

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
Superoxide dismutase
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

2

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

3

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

4

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

5

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

6

Description
The ratio of reduced glutathione to oxidized glutathione
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula

7

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

8

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

9

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

10

Description
Malondialdehyde
Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Colorimetric

11

Description

Ratio of malondialdehyde to total antioxidant capacity

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Formula

12

Description

Total antioxidant gap

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Formula

13

Description

Total Thiol

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Colorimetric

14

Description

C-reactive protein

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Turbidimetry

15

Description

The ratio of C-reactive protein to albumin

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Formula

16

Description

The ratio of blood urea nitrogen to albumin

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Formula

17

Description

Albumin bilirubin score

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Formula

18

Description

Triglyceride-Glucose index

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Formula

19

Description

Ovary volume

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Ultrasonography

20

Description

The rate of hirsutism

Timepoint

Before and 12 weeks after the start of the intervention

Method of measurement

Modified Ferriman-Gallwey scoring scale

21

Description

Menstrual frequency

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).

22

Description

Tumor necrosis factor-alpha

Timepoint

Before and 12 weeks after the start of the intervention(measuring on 40 patients)

Method of measurement

ELISA

23

Description

Interleukin-6

Timepoint

Before and 12 weeks after the start of the intervention(measuring on 40 patients)

Method of measurement

ELISA

24

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

25

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

26

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

27

Description
High Density Lipoprotein
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

28

Description
low Density Lipoprotein
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Colorimetric

29

Description
Cholesterol to high density lipoprotein ratio
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula

30

Description
Triglyceride to high density lipoprotein ratio
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula

31

Description
The ratio of low-density lipoprotein to high-density lipoprotein
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula

Secondary outcomes

1

Description
Body mass index
Timepoint
Before and 12 weeks after the start of the intervention
Method of measurement
Formula

Intervention groups

1

Description
Intervention group: One capsule Arctium Lappa root powder (460 mg) per day for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: One capsule placebo starch (460 mg) per day for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Hanieh Taheri
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Imam Khomeini Street, Shora Square, Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Research@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
Hanieh Taheri
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Master Student
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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
Ali Khosrowbeygi a.khosrowbeygi@arakmu.ac.ir
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