

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effect of medroxyprogesterone acetate and black seed extract on the symptoms of polycystic ovary syndrome in adolescent girls

Protocol summary

Study aim

Determining the effect of medroxyprogesterone acetate and black seed extract on the severity of symptoms of polycystic ovary syndrome in adolescent girls

Design

Clinical trial, with parallel groups, randomized, on 116 patients. Quadruple permutation blocks are used for randomization.

Settings and conduct

Clinics and offices of gynecologists

Participants/Inclusion and exclusion criteria

Age range 12-18 years 2 years have passed since the start of menstruation Having the written consent of the teenager and his parents to participate in the study Ultrasound-confirmed polycystic ovary according to the Amsterdam criteria Absence of other causes of hyperandrogenism Not using hormonal drugs in the last three months Not taking drugs that interact with medroxyprogesterone acetate Not suffering from diseases such as hypothyroidism, hyperprolactinemia with kidney, heart, liver, bone diseases, pituitary tumor, cancer and diabetes (based on clinical history and participants' statements) Not using tobacco and drugs (based on the participants' statements) No history of surgery on one or both ovaries No history of stressful events in the past three months (such as the death of a family member, accident, sexual violence, robbery) according to the teenager's self-report and parents' statements.

Intervention groups

The intervention group will receive black cumin and the control group will receive medroxyprogesterone

Main outcome variables

Severity of polycystic ovary syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221017056209N1**

Registration date: **2022-11-22, 1401/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name

Akram Ashoori

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of medroxyprogesterone acetate and black seed extract on the symptoms of polycystic ovary syndrome in adolescent girls

Public title

Comparison of the effect of medroxyprogesterone acetate and black seed extract on the symptoms of polycystic ovary syndrome in adolescent girls

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 12-18 years 2 years have passed since the start of menstruation Having the written consent of the teenager and her parents to participate in the study Ultrasound-confirmed polycystic ovary according to the Amsterdam criteria Absence of other causes of hyperandrogenism such as non-classical congenital adrenal hyperplasia, Cushing's syndrome (based on clinical history and participant's symptoms and statements), body mass index 25-19 Not using hormonal drugs in the last three months Not taking drugs that interact with medroxyprogesterone acetate, including amphetamine, thyroid drugs, diphenhydramine, ciprofloxacin, clofin, duloxetine, estradiol, omega-3 saturated fatty acids, lesilalopram, pregabalin, levonorgestrel, montelukast, levothyroxine, testosterone, cyanocobalamin. , ascorbic acid, colcalcinol, multivitamin, sertraline, cetirizine Insensitivity to black seed and medroxyprogesterone (according to the comment of the participant) Not suffering from diseases such as hypothyroidism, hyperprolactinemia with kidney, heart, liver, bone diseases, pituitary tumor, cancer and diabetes (based on clinical history and participants' statements) Not using tobacco and drugs (based on the participants' statements) No history of surgery on one or both ovaries There is no history of stressful events in the last three months (such as the death of a family member, accident, sexual violence, robbery) according to the teenager's self-report and parents' statements.

Exclusion criteria:

Unwillingness to participate in the study

Age

From **12 years** old to **18 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done based on the randomization method of permutation blocks with variable sizes of 2 and 4. In this way, the randomization list will be determined (www.sealedenvelope.com)by the analyst. Opaque sealed envelopes with random sequence will be used for concealment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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

Imam khomeini

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2022-08-26, 1401/06/04

Ethics committee reference number

IR.GMU.REC.1401.080

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**

Severity of polycystic ovary syndrome symptoms

Timepoint

The beginning of the study (before the intervention), 16 weeks after the intervention

Method of measurement

Ovarian volume ultrasound, LH test, GTT 1hr, GTT 2hr, total testosterone, fasting blood sugar, dihydroepiandrosterone sulfate or DHEA-S and androgen levels (testosterone and dihydroepiandrosterone sulfate or DHEA-S)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Receiving medroxyprogesterone, taking 10 mg medroxyprogesterone tablets every month once a day from the 14th day of the cycle for 10 nights for 4 months

Category

Treatment - Drugs

2

Description

Intervention group: Receiving black seeds, two capsules of 500 mg (1000 mg) of black seeds continuously until the fourth month from the beginning of the intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Clinic of Allameh Bahloul Gonabadi Hospital and gynecology clinics of Gonabad city

Full name of responsible person

Narjes Bahri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

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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

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

Akram Ashouri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

Narjes Bahri

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Email

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

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

Yes - There is 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

Print the article

When the data will become available and for how long

After printing the article

To whom data/document is available

All people

Under which criteria data/document could be used

Conduct future studies

From where data/document is obtainable

internet

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

Searching for article titles on the Internet

Comments