Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

Phone
+98 51 5722 5027

Email address
a.ashoori369@gmail.com

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
Street address
Imam khomeini
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Email
nargesbahri@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Narges Bahri
Street address
Imam Khomeini
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793781
Phone
+98 51 5722 0578
Email
nargesbahri@yahoo.com
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
Street address
Imam Khomeini
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Email
a.ashouri1369@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Narjes Bahri
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery

Street address
Hmam Khomeini
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Email
nargesbahri@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Akram Ashouri
Position
Sudent
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Imam Khomeini
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793918
Phone
+98 51 5722 3028
Email
a.ashouri1369@gmail.com

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
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