Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of nigella sativa oil on serum levels of Total antioxidant capacity(TAOC) and Malondialdehyde(MDA) in patients with polycystic ovarian syndrome

Protocol summary

Study aim

Determining the effect of nigella sativa oil on serum level of Malondialdehyde(MDA) , Total antioxidant capacity(TAOC) and lipid profile in patient with polycystic ovarysyndrome.

Design

The study is conducted in an interventional (phase 3 clinical trial) and on 60 patients with polycystic syndrome .patients will be randomly divided into two groups of 30 using envelopes containing medicine and placebo and two blinders.the case groups will be given black seed oil at dose of 1000 mg daily for 12 weeks, and the control group will be given a placebo drug at the same dose and time

Settings and conduct

The study is conducted on 60 patients with polycystic syndrome referred to the obstetrics and Gynecology clinic of Alavi Hospital in ardabil.patients will be randomly divided into two groups. black seed oil will be given to the case group for 12 weeks and placebo to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Menstural cycle disorders,clinicalor biochemical hyperandrogenism and sonographic appearance of polycystic syndrome Exclusion criteria:Type 2 diabets,adernal hyperplasia,thyroid diseases,autoimmune diseases and hyperprolactinemia,diet and special drug use

Intervention groups

The case group received 12 weeks of blackseed oil with a dose of 1000 mg daily and the placebo drug control group with the same dose and time

Main outcome variables

Malondialdehyde(MDA),Total antioxidant capacity(TAOC),Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231124060163N1**
Registration date: **2023-12-06, 1402/09/15**
Registration timing: **prospective**

Last update: **2023-12-06, 1402/09/15**
Update count: **0**

Registration date

2023-12-06, 1402/09/15

Registrant information

Name

Negin Panahikaleybar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of nigella sativa oil on serum levels of Total antioxidant capacity(TAOC) and Malondialdehyde(MDA) in patients with polycystic ovarian syndrome

Public title
Effect of Nigella sativa oil in patients with polycystic ovary

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Oligomenorrhea or lack of ovlation polycystic ovaries based on ultrasound Androgenic hormone changes in laboratory or clinical form (the presence of hirsutism)

Exclusion criteria:
Type 2 diabets Thyroid disease Adernal hyperplasia Autoimmune disease Hyperprolactinemia People with structured physical activity or scheduled exercise If three months before entering the study,they use a special diet or special drugs that may affect the results ,they will be excluded from the study ,such as anti-obesity drugs,induction ovulation,antidepressants,insulin sensivity,oral contraceotives,asprin,and anti-prostaglandin drugs If there are signs of pregnancy,they will be excludedfrom the study

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Using envelopes (A and B) containing medicine and placebo,theywill be randomly divided into two groups.Basedon the calculated sample size,30envelops A and 30 envelops B are placed in a lottery container,and then the envelops are randomly removed from the container without replacement and the created sequence will be recorded.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, double-blind will be used so that patientand the student who providesthe envelope to the patient will be blind to the content of the envelops (intervention or placebo)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardabil university of Medival sciences

Street address
Faculty of medicine,1st floor,university street, 8599156189

City
Ardabil

Province
Ardabil

Postal code
8599156189

Approval date
2023-08-17, 1402/05/26

Ethics committee reference number
IR.ARUMS.REC.1402.128

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
Malondialdehyde(MDA)

Timepoint
Before and after 12 weeks of intervention

Method of measurement
Determination of serum level

2

Description
Total antioxidant capacity(TAOC)

Timepoint
Before and after 12 weeks of intervention

Method of measurement
Determination of serum level

Secondary outcomes

1

Description
Triglyceride

Timepoint
Before and after 12 weeks of intervention

Method of measurement
Determination of serum level

2

Description
cholesterol
Timepoint
Before and after 12 weeks of intervention
Method of measurement
Determination of serum level

3

Description
High-density lipoprotein (HDL)
Timepoint
Before and after 12 weeks of intervention
Method of measurement
Determination of serum level

4

Description
Low-density lipoprotein (LDL)
Timepoint
Before and after 12 weeks of intervention
Method of measurement
Determination of serum level

Intervention groups

1

Description
Intervention group:subjects receiving black seed oil,In this group,subgects will receive capsules containing black seed oil with a dose of1000 mg per day orally for three months.Black seed oil capsules will be provided by Barij Essans oil company(kashan).
Category
Treatment - Drugs

2

Description
Control group: subjects receiving placebo capsules,in this group ,subjects will receive capules containing placebo,which are similar to capsules containing black seed oil in terms of shape,color and side ingredients,orally daily for three months.placebo capsules will be provided from Barij Essans oil company(kashan).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi Ardabil Hospital
Full name of responsible person
SHahla Farzipour
Street address
Sport field-Alavi Hospital
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
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Street address
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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
Ardabil University of Medical Sciences
Proportion provided by this source
80
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
Ardabil University of Medical Sciences

Full name of responsible person
SHahla Farzipour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
SHahla Farzipour

Position
Assistant Professor

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Person responsible for updating data

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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
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
Demographic,clinical and outcome data

When the data will become available and for how long
No time limit

To whom data/document is available
Journal if needed

Under which criteria data/document could be used
With permission from the university Ethics committee

From where data/document is obtainable
corresponding

What processes are involved for a request to access data/document
A written request from the relevent unit and permission from the university Ethics committee

Comments