# 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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+98 41 4444 0168

**Email address**

negin.panahi69@gmail.com

**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
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## Sponsors / Funding sources

**1**

**Sponsor**
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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

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## Person responsible for updating data

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**Position**
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Gynecology and Obstetrics

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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**