

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The effect of green coffee supplementation on androgens levels in patients with polycystic ovary syndrome

#### Protocol summary

##### Study aim

Effect of green coffee supplement on the level of androgen in women with poly-cystic ovary syndrome

##### Design

This study is a Double-blind study clinical trial with parallel groups that is divided into two groups of treatment and control. The study groups are women with polycystic ovarian syndrome. In this study, a randomized block method was used in which encoded patients Each patient is given codes for each patient, and patients are divided into two groups. The sample size is 40.

##### Settings and conduct

Sampling from Shariati clinic has been done

##### Participants/Inclusion and exclusion criteria

Entry requirements Metformin, Collofen, Letrozole, HMG and HCG, Folic Acid The age group is 20 to 40 years old. Body mass index has 18.5-34.9 kg / m<sup>2</sup> or more. No entry Having a decision to have a pregnancy during the study period Having sensitivity and intolerance to the green coffee supplement There are thyroid and renal disorders Consuming food supplements

##### Intervention groups

The intervention group received green coffee pills and the control group received the placebo

##### Main outcome variables

Changes of FREE TESTOSTERON-ANDRESTANDION-DIHYDROTESTOSTERO -LDL-CHOLESTEROL-TG\_FBS-INSULIN and increase of HDL

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180711040428N1**

Registration date: **2018-10-15, 1397/07/23**

Registration timing: **retrospective**

Last update: **2018-10-15, 1397/07/23**

Update count: **0**

##### Registration date

2018-10-15, 1397/07/23

##### Registrant information

###### Name

Ahmad Mousavi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3721 2586

###### Email address

ahmad.mousavi@srbiau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-22, 1397/04/31

##### Expected recruitment end date

2018-07-28, 1397/05/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of green coffee supplementation on androgens levels in patients with polycystic ovary syndrome

##### Public title

The effect of green coffee supplementation on patients with polycystic ovary syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Having polycystic ovarian syndrome Age group between 20 and 40 years old Use of pcos syndrome drugs Body mass index from 18.5 to 39.9

**Exclusion criteria:**

The desire to get pregnant while studying Being pregnant Thyroid and renal failure Consuming food supplements Coffee susceptibility Acute abnormalities in women with polycystic ovary syndrome during the research period

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

randomize block design

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The complementary method in this study is double-blind, so that the researcher and the participants are not supplemented (placebo or green coffee), and the other person is responsible for the coding of supplements and placebo, which is an add-on supplement Each group receives (intervention or control) is informed. The patients are then supplemented by a researcher who does not have supplemental information, and at the end of the laboratory assessment is done blind, because the lab does not have any knowledge of the study. After evaluations and at the end of the study, the type of encoded supplements is revealed to the researcher.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee on Biomedical Research, Research Branch, Islamic Azad University

**Street address**

Azad

**City**

Tehran

**Province**

Tehran

**Postal code**

11111111111111111111

**Approval date**

2018-03-04, 1396/12/13

**Ethics committee reference number**

IR.IAU.SRB.REC.1396.108

**Health conditions studied**

1

**Description of health condition studied**

Polycystic ovary syndrom

**ICD-10 code**

E28.2

**ICD-10 code description**

Polycystic ovarian syndrome

**Primary outcomes**

1

**Description**

Androgens

**Timepoint**

Before starting the study and 60 days after taking the green coffee pill

**Method of measurement**

Elisa device

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: The blood samples are taken prior to the intervention and the serum is isolated. Then, the level of androgens and lipid and sugar determinants is measured by ELISA method, and this group will receive 2 tablets of 500 milligrams of green coffee for the period of 60 days with lunch The blood samples are taken again and the factors listed above are measured again. The main ingredients are green chlorine acid and caffeine. For each person, two training sessions are provided.

**Category**

Treatment - Other

2

**Description**

Control group:The blood samples are taken before the intervention and the serum is isolated. Then, the level of androgens and lipid and sugar determinants is measured by ELISA method, and this group received 2 500 mg

tablets of 500 mg of placebo for the 60 day lunch meal for 60 days. The blood samples are taken again and the level of the factors mentioned above is measured. The main place of placebo is flour. Each training session is provided for each person.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shariati Clinic

**Full name of responsible person**

Ahmad mousavi

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Karegar

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**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

احمد موسوی

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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**

Islamic Azad University

**Proportion provided by this source**

30

**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**

Islamic Azad University

**Full name of responsible person**

Ahmad saedi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

### Contact

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Islamic Azad University

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**Other areas of specialty/work**

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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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All sections of the protocol and analyzes of the study and clinical reports will be shared

**When the data will become available and for how long**

It is currently unclear

**To whom data/document is available**

All people are allowed to use this documentation

**Under which criteria data/document could be used**

Sometimes people can use this document for their purpose to use this documentation of therapeutic and research applications

**From where data/document is obtainable**

Can access documents through email

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

The applicant can receive the documentation after identifying his identity

**Comments**