Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 / m2 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)
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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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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