

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of green tea tablet on inflammatory markers C-reactive protein, interleukin-6, tumor necrosis factor alpha, insulin, fasting blood glucose and blood lipid profile in women with polycystic ovary syndrome.

Protocol summary

Summary

Green tea contains polyphenols such as catechin that have protective effects against a wide range of diseases associated with chronic inflammation. Given that chronic low-grade inflammation is associated with polycystic ovary syndrome and the inflammatory condition can eventually lead to heart disease, so it is important to consume some foods that could be effective on reduction of inflammation in these patients. This study was designed to investigate the effect of green tea tablets intake on inflammatory factors and lipid profile and blood sugar levels in patients with polycystic ovary syndrome. Inclusion criteria are Patients with this syndrome with age range 55-18 years, BMI 40-25 range and the key exclusion criteria is having other diseases. sample size is 50 that will be divided into two groups (green tea tablets and placebo groups). The period of intervention is 45 days. The primary outcomes are fasting blood glucose, lipid profile (LDL-C, TG, HDL-C and total cholesterol), and inflammatory factors hs-CRP, IL-6 and TNF- α .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021816123N4**

Registration date: **2015-03-11, 1393/12/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-11, 1393/12/20

Registrant information

Name

Sima Jafarirad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8317

Email address

jafarirad-s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-03-08, 1393/12/17

Expected recruitment end date

2015-07-08, 1394/04/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of green tea tablet on inflammatory markers C-reactive protein, interleukin-6, tumor necrosis factor alpha, insulin, fasting blood glucose and blood lipid profile in women with polycystic ovary syndrome.

Public title

The effect of green tea tablets in the treatment of polycystic ovary syndrome.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 55-18, 40-25 Body Mass Index, a willingness to participate in the study, having two

features of the following three characteristics: oligo ovulation or anovulation, clinical or biochemical evidence of hyperandrogenism, having more than 12 but less than 10 mm immature follicles in each ovary. Exclusion criteria: no appropriate corporation; any other disease, pregnancy and lactating

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

The Ethics Committee, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Blvd.

City

Ahvaz

Postal code**Approval date**

2015-01-17, 1393/10/27

Ethics committee reference number

ajums.rec.1393.406

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Stein-Leventhal syndrome

Primary outcomes**1****Description**

fasting blood glucose

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

2**Description**

Insulin level

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

3**Description**

LDL

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

4**Description**

HDL

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

5**Description**

TG

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

6**Description**

total Cholesterol

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

7

Description

hs-CRP

Timepoint

at the first and at the end of intervention period

Method of measurement

Elisa

8

Description

IL-6

Timepoint

at the first and at the end of intervention period

Method of measurement

Elisa

9

Description

TNF- α

Timepoint

at the first and at the end of intervention period

Method of measurement

Elisa

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: diet controlling;tablets containing 50 mg of green tea polyphenols 4 per day for 45 days.

Category

Treatment - Other

2

Description

Control:diet controlling for 45 days .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecologist's office

Full name of responsible person

Doctor P. Padfar

Street address

City

Dezful

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology

Street address

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Blvd.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nutrition and Metabolic Disease Research Center, Ahvaz Jundishapur University of Medical Sciences, A

Full name of responsible person

Dr. Sima Jafarirad

Position

PhD

Other areas of specialty/work

Street address

Nutrition and Metabolic Disease Research Center, Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Blvd.

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences,
paramedics schools

Full name of responsible person

Esmat mombeni

Position

Master Student of Nutrition

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
University City, Golestan Blvd, paramedics schools

City

Ahvaz

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty