Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of green tea and placebo on weight loss, Insulin Resistance Index and Testosterone in overweight and obese patients with polycystic ovary syndrome

Protocol summary

Summary

PCOS, is a common disorder that almost 10 percent of women of childbearing age are affected. This syndrome is the most important cause of oligoovulation and unovulation in infertile women and in the general population and is one of the most common endocrine disorders.This syndrome, causes infertility and potentially serious metabolic risks in women. Obesity is an important risk factor in women with polycystic ovary syndrome which causes many symptoms of the syndrome. Studies have shown that weight loss of 5% of initial weight within 6 months in 75% of women have reduced levels of insulin and free testosterone. At least 5%weight loss of initial body weight for achieving clinical and biochemical benefits, including increased rates of pregnancy is required. Green tea is produced with processing the leaves of tea immediately after collection. All polyphenolic components of tea are catechin degradation which produce heat through inhibition of norepinephrine. Another mechanism that may cause catechin can inhibit angiogenesis and production adipose tissue and thereby reduce the weight. Therefore, managing PCOS with emphasize on lifestyle changes and weight loss in obese and overweight women is important. Accordingly, researchers intend to study the effects of green tea on weight loss and hormonal parameters in overweight and obese patients with PCOS do. In this double-blind (neither the patient nor the person providing medicine to the patient is not aware of the group assignment as drug and placebo. As drug and placebo are named as A and B, and only the researcher is aware of them) randomized (over time, as patients are entered into study, will be assigned one to control group and another one to intervention group) clinical trial groups, 70 women with PCOS and overweight or obesity will be randomly divided into two groups. Our study population are patients with PCOS referred to Alzahra University Hospital in the Isfahan city aged between 20 and 40 years. The intervention group will receive tea tablets 500 mg (2 times a day for 12 weeks) and the control group placebo. Body mass index, free testosterone and serum insulin concentrations will be measured by Enzyme-Linked Immunosorbent Assay (ELIZA) method. Fasting serum glucose was measured by the enzyme-calorimetric method and insulin resistance index (HOMA-IR) will be measured by the calculation of relevant equation at baseline and after twelve weeks in the two groups. None of the women in the study, do not take medicine due to infertility or hirsutism. In addition, according to thermogenesis effect of green tea on weight loss, physical activity levels of patients will be determined and considered as a moderating factor.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2013111015349N1**
Registration date: **2014-01-20, 1392/10/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-20, 1392/10/30

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
Isfahan University of Medical Sciences

Expected recruitment start date
2013-12-06, 1392/09/15
Expected recruitment end date
2014-06-05, 1393/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of green tea and placebo on weight loss, Insulin Resistance Index and Testosterone in overweight and obese patients with polycystic ovary syndrome

Public title
Green tea effect on weight loss and hormone levels in polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: - Infected samples PCOS is registered by the gynecologist. - Persons between the age group of 40-20 years are. Exclusion criteria: -Patients have the History of heart disease - cardiovascular disease, diabetes or other metabolic diseases. -Patients who do not wish to be excluded - Patients with weight loss drugs insulin sensitizer drugs and contraceptive use - Patients who are treated with weight loss diets -Patients engaged in heavy exercise
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjarib Blvd., Isfahan
City
Isfahan
Postal code
-
Approval date
2013-10-23, 1392/08/01
Ethics committee reference number
11/2936/د

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Sclerocystic ovary syndrome

Primary outcomes

1

Description
Body mass Index
Timepoint
before intervention & 12 weeks after intervention
Method of measurement
weight with one hundred grams and height with 0/5 cm of measurement sensitivity will be measured and BMI by dividing weight in kilograms by the square of height (m) shall be calculated

2

Description
Free Testosterone
Timepoint
before intervention & 12 weeks after intervention
Method of measurement
dl- chemenoassay

3

Description
Insulin resistance index(HOMA-IR)
Timepoint

before intervention & 12 weeks after intervention

Method of measurement

insulin resistance index (HOMA-IR) was measured by the calculation of relevant equation.

4

Description

Fasting serum glucose

Timepoint

before intervention & 12 weeks after intervention

Method of measurement

enzyme-calorimetric method

5

Description

fasting serum insulin concentrations

Timepoint

before intervention & 12 weeks after intervention

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELIZA) method

Secondary outcomes

empty

Intervention groups

1

Description

Green Tea Tablets(Green Teadin) from Dinah Industrial Complex of Iran 500 mg 2 times a day for 12 weeks(Tablet powder is poured into capsules)

Category

Treatment - Drugs

2

Description

placebo(Capsules containing flour) 2 times a day for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra University Hospital

Full name of responsible person

Street address

Alzahra University Hospital, Sofe Blvd., Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Peyman Adibi

Street address

Vice chancellor for research, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

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, Isfahan 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

Name of organization / entity

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Position

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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