

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial comparing the effect of Green Tea extract and placebo on serum lipid profiles in postmenopausal women

Protocol summary

Summary

This study investigated the effects of Green Tea extract on serum lipid profiles in postmenopausal women. The subjects are women 45 to 65 years old with at least one year of their natural menstrual passes and history of any Thyroid disease, Diabetes, Stroke, Coronary artery disease, Liver disease, Gallbladder removal or taking prescription drugs such as, Aspirin, female hormones, Lithium, Corticosteroids, Warfarin and supplements containing antioxidants do not report. Intended sample size for this study, 100 women volunteered that the people referred to clinic are selected. First, any eligible candidate (according to inclusion and exclusion criteria) to measure blood lipid profiles (Total Cholesterol, Triglycerides, Low-Density Lipoprotein and High-Density Lipoprotein) will be taken. Reported in at least one case of borderline values of individual profiles will be selected as the study sample. Sampling will be conducted until the sample is completed. Because the study is double-blind, packets are encoded capsules (each capsule containing placebo or 400 mg of green tea extract) are distributed randomly among the subjects. Domestic drug consumption is 2 capsules after breakfast and dinner daily. Tests will be repeated again one month after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021816625N1**

Registration date: **2014-05-23, 1393/03/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name

Samaneh Movahedi zadeh

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Ahvaz, Jundishapur University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

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

Clinical trial comparing the effect of Green Tea extract and placebo on serum lipid profiles in postmenopausal women

Public title

Effects of Green Tea on blood lipids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Over at least one year of normal menstruation; Report one or more of the lipid parameters in the borderline range; Age range 45 to 65 years.
Exclusion criteria: Thyroid disorders including

Hypothyroidism and Hyperthyroidism, Diabetes, Hypertension, Kidney failure, Liver disease, Coronary artery disease and cancer; Removal of the Gallbladder; A history of Stroke or Heart attack; Consumption of herbal medicines to improve metabolic abnormalities and Hypertension in three months; Following the departure of abnormal uterus and ovaries menopause; Smoking, drugs or Alcohol; Caffeine sensitivity; Use of medications such as Aspirin, female hormones, Lithium, corticosteroids, Warfarin, and supplements containing antioxidants; Non- pharmacological interventions to improve metabolic disorders such as regular exercise, Yoga and acupuncture; Regular consumption of Green Tea daily

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

Ahvaz, Jundishapur University of Medical Sciences

Street address

Golestan boulevard

City

Ahvaz

Postal code

6135715794

Approval date

2013-09-28, 1392/07/06

Ethics committee reference number

ajums.REC.1392,216

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

hyperlipidaemia

ICD-10 code

E78.2

ICD-10 code description

Hypercholesterolaemia with endogenous hyperglyceridaemia

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

Total Cholesterol

Timepoint

Before the intervention and one month after intervention

Method of measurement

Measurement of serum Total Cholesterol levels after 12 hours of fasting

2**Description**

Triglycerides

Timepoint

Before the intervention and one month after intervention

Method of measurement

Measurement of serum Triglycerides levels after 12 hours of fasting

3**Description**

Low Density Lipoprotein (LDL)

Timepoint

Before the intervention and one month after intervention

Method of measurement

Measurement of serum Low Density Lipoprotein (LDL) levels after 12 hours of fasting

4**Description**

High Density Lipoprotein (HDL)

Timepoint

Before the intervention and one month after intervention

Method of measurement

Measurement of serum High Density Lipoprotein (HDL) levels after 12 hours of fasting

Secondary outcomes**1****Description**

Blood pressure

Timepoint

Before the intervention, 2 weeks and 4 weeks after intervention

Method of measurement

Medical manometer

2

Description

Fasting blood sugar

Timepoint

Before the intervention and one month after intervention

Method of measurement

Measurement of serum Sugar levels after 12 hours of fasting

3

Description

Weight

Timepoint

Before the intervention and one month after intervention

Method of measurement

Analog scale

Intervention groups

1

Description

Green tea extract 800 mg per day in two capsules after breakfast and dinner

Category

Treatment - Drugs

2

Description

In two placebo capsules per day after breakfast and dinner

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center Shahrivar 17

Full name of responsible person

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz, Jundishapur University of Medical Sciences

Full name of responsible person

Dr Nader Saki

Street address

Golestan boulevard

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Name of organization / entity

Ahvaz, Jundishapur University of Medical Sciences

Full name of responsible person

Samaneh Movahedi zadeh

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Phone

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