

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of oral sachet containing extracts of *Garcinia cambogia* and *Plantago psyllium* with capsules containing extract of Green tea and Green coffee on weight of obese and over weight people

Protocol summary

Study aim

The effect of oral sachet containing extracts of *Garcinia cambogia* and *Plantago psyllium* with capsules containing extract of Green tea and Green coffee and placebo on weight of over weight and obese people in Beheshti nutrition therapy center The effect of oral sachet containing extracts of *Garcinia cambogia* and *Plantago psyllium* with capsules containing extract of Green tea and Green coffee and placebo on blood lipid level(Cholesterol, Triglyceride and High and low density lipoprotein), fasting blood glucose, liver enzymes and high sensitive-Critical Reactive Protein and plasma total antioxidant

Design

Randomized clinical trial, controlled with placebo, parallel, double blind, single central

Settings and conduct

This study is a clinical trial on 82 patients BMI>25, aged 18 to 50 who refers to Kashan Beheshti nutrition therapy center. Individuals based on table of random numbers will be divided to one of the groups received herbal or placebo treatment plus standard treatment for 8 weeks randomly . Herbal drug and placebo are presented in the same package and the physician , patients, researcher and statistical analyst are blind .After analyzing data, codes will be decoded.

Participants/Inclusion and exclusion criteria

Inclusion criteria:18-50 years old.BMI>25 exclusion criteria: metabolic disorders; nutritional supplements; pregnancy; lactation; thyroid and parathyroid disease.

Intervention groups

Intervention group: Weight loss diet+regular physical activity+ oral sachet containing extracts of *Garcinia cambogia* and *Plantago psyllium* half an hour before meals and oral capsules containing extract of Green tea and Green coffee after each meal twice a day.each time1. for 8 weeks Control group: Weight loss

diet+regular physical activity+ oral placebo sachet half an hour before meals and placebo capsules after each meal twice a day.each time1. for 8 weeks

Main outcome variables

At the end of study: changes of weight: blood Cholesterol:Triglyceride: high and low density lipoprotein: fasting blood glucose: liver enzymes: high sensitive-Critical Reactive Protein and plasma total antioxidant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N25**

Registration date: **2018-02-26, 1396/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-26, 1396/12/07**

Update count: **0**

Registration date

2018-02-26, 1396/12/07

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 36 1555 0021

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taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral sachet containing extracts of Garcinia cambogia and Plantago psyllium with capsules containing extract of Green tea and Green coffee on weight of obese and over weight people

Public title

The effect of oral sachet containing extracts of Garcinia cambogia and Plantago psyllium with capsules containing extract of Green tea and Green coffee on obesity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18-50 years old BMI>25

Exclusion criteria:

metabolic disorders nutritional supplements pregnancy and lactation thyroid and parathyroid disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized based on table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Coding and similar packaging. The physician, patient, researcher and statistical analyzer are blind. At the end of the study and analysis of data, codes are decoded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University Of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2018-01-08, 1396/10/18

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1396.28

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

Overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

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

Weight changes in people with BMI greater than 25.

Timepoint

At the beginning of the study, the end of the fourth week, the end of the study

Method of measurement

digital scale

2**Description**

lipid profile (Cholesterol, Triglyceride and High and low density lipoprotein)

Timepoint

Baseline and End-of-trial

Method of measurement

fasting blood sample

3**Description**

fasting blood glucose

Timepoint

Baseline and End-of-trial

Method of measurement

fasting blood sample

4

Description

liver enzymes

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

5

Description

high sensitive-Critical Reactive Protein

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

6

Description

plasma total antioxidant

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Weight loss diet+regular physical activity+ oral sachet containing extracts of Garcinia cambogia and Plantago psyllium half an hour before meals and oral capsules containing extract of Green tea and Green coffee after each meal twice a day.each time1. for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Weight loss diet+regular physical activity+ oral placebo sachet half an hour before meals and placebo capsules after each meal twice a day.each time1. for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Beheshti nutrition therapy center

Full name of responsible person

Dr Mohsen Taghizadeh

Street address

Shahid beheshti hospital, Ghotbe Ravandi Boulevard,
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<http://www.beheshti.kaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Gholam Ali Hamidi

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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

Kashan University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity
Barij Research Center of Medicinal Herbs
Full name of responsible person
Laleh Hejazi
Street address
Kashan Mashhad Ardehal Road, KM44
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Isfahan
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Fax
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Email
info@barijessence.com
Web page address
http://www.barijessence.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barij Research Center of Medicinal Herbs

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr Mohsen Taghizadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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کارشناس تحقیقات بالینی

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Midwifery

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available