Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 36 1555 0021

Email address

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
Isfehan
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, Kashan
City
Kashan
Province
Isfehan
Postal code
87159/81151
Phone
+98 31 5554 0026
Fax
+98 31 5554 8900
Email
mohsenta44@yahoo.com
Web page address
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
Street address
Kashan university of Medical Science, Kashan
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5554 2999
Fax
+98 31 5557 5057
Email
hamiidi@yahoo.com
Web page address
http://kaums.ac.ir
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
City
Kashan, Mashhad ardehal
Province
Isfehan
Postal code
1178
Phone
+98 86 4854 0000
Fax
+98 86 4436 2187
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
Street address
Kashan University Of Medical Sciences, Kashan
City
Kashan
Province
Isfehan
Postal code
88715973474
Phone
+98 31 5562 0608
Email
mohsenta44@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Mohsen Taghizadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Medicine, Qotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
88715973474
Phone
+98 31 5562 0608
Fax
+98 31 1555 1112
Email
taghizadeh_m@kaums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Barij Research Center of Medicinal Herbs
Full name of responsible person
Mahnaz Mahlouji
Position
کارشناس تحقیقات بالینی
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Kashan Mashhad Ardehal Road, KM44
City
Kashan Mashhad Ardehal
Province
Isfehan
Postal code
1178

Phone
+98 86 4854 0000
Email
mahnaz.mahlouji@yahoo.com
Web page address
http://www.barijessence.com

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