

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Evaluation of the effect of calorie restricted diet adjunctive with green coffee been extract supplementation on some metabolic factors, anthropometric measures, plasma free fatty acids, visceral fat indice and serum adipocytokins in obese women.

Protocol summary

Summary

This is an interventional study with the goal of evaluation of the effect of calorie restricted diet adjunctive with green coffee been extract supplementation on some metabolic factors, anthropometric measures, plasma free fatty acids, visceral fat indice and serum adipocytokins in obese wome. The Inclusion criteria is females, age 20-45 years, Before menopause, fat mass index more of the equal with 7.8 and 9.9 in ages 20-34 and 35-45 and willingness to cooperate in the study and the exclusion criteria is being under weight loss in 6 months, pregnancy, lactation, menopause, endocrine diseases, cardiovascular disease, liver disease, kidney disease, Thyroid disease, consumption of steroids drugs and Hormone therapy and intake of multivitamin or mineral or antioxidan complete. In this study 7 days food record will use to evaluate the dietary intake. Obese cases selected based on fat mass index and will be under the 8-week treatment period. In case group the subjects will be under the intake of green coffee been extract supplementation adjunctive with calorie restricted diet and the control group will be under the intake of placebo adjunctive with calorie restricted diet. metabolic factors and anthropometric measures will be measured at the first and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081910181N7**

Registration date: **2015-09-26, 1394/07/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-26, 1394/07/04

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

The present study will be supported by a grant from the Vice-chancellor for Research Ahvaz Jondishapoor University of Medical Sciences

Expected recruitment start date

2015-10-02, 1394/07/10

Expected recruitment end date

2016-02-29, 1394/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of calorie restricted diet adjunctive with green coffee been extract supplementation on some metabolic factors, anthropometric measures, plasma free fatty acids,

visceral fat indiceand serum adipocytokins in obese women.

Public title

The effect of calorie restricted diet adjunctive with green coffee bean extract on obesity and inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: females; age 20-45 years; Before menopause; fat mass index More of the equal with 7.8 and 9.9 in ages 20-34 and 35-45; Willingness to cooperate in the study the Exclusion criteria: Being under weight loss in 6 months; pregnancy; lactation; menopause; Endocrine diseases; cardiovascular disease; liver disease; kidney disease; Thyroid disease; consumption of Steroids drugs and Hormone therapy; intake of multivitamin or mineral or antioxidan complete

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapoor University of Medical Sciences

Street address

Ahvaz Jondishapoor University of Medical Sciences

City

Ahvaz

Postal code

Approval date

2015-07-25, 1394/05/03

Ethics committee reference number

ir.ajums.rec.1394.256

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Fat Mass Index

Timepoint

The beginning and end of the study

Method of measurement

Body Composition Analyser

2

Description

Visceral Fat

Timepoint

The beginning and end of the study

Method of measurement

Calculation

3

Description

Free Faty Acid

Timepoint

The beginning and end of the study

Method of measurement

Blood test

4

Description

Plasma leptin

Timepoint

The beginning and end of the study

Method of measurement

Blood test

5

Description

Adiponectin

Timepoint

The beginning and end of the study

Method of measurement

Blood test

6

Description

Total Cholesterol

Timepoint

The beginning and end of the study
Method of measurement
Blood test

7

Description
LDL Cholesterol
Timepoint
The beginning and end of the study
Method of measurement
Blood test

8

Description
HDL Cholesterol
Timepoint
The beginning and end of the study
Method of measurement
Blood test

9

Description
Triglycerides
Timepoint
The beginning and end of the study
Method of measurement
Blood test

10

Description
Blood Glucose
Timepoint
The beginning and end of the study
Method of measurement
Blood test

11

Description
Plasma Insulin
Timepoint
The beginning and end of the study
Method of measurement
Blood test

Secondary outcomes

1

Description
Blood Pressure
Timepoint
The beginning and end of the study
Method of measurement
Pressure indicatore

2

Description

Waist Circumference
Timepoint
The beginning and end of the study
Method of measurement
measurment

Intervention groups

1

Description
400 mg Green Coffee bean extract one in day 8 weeks
Category
Treatment - Drugs

2

Description
placebo 1 gr one in day 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Majid Mohamadshahi diet therapy clinic
Full name of responsible person
Mehnoosh Samadi
Street address
Golestan Highway, Ahvaz Jondishapoor University of Medical Sciences, Ahvaz, Iran.
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jondishapoor University of Medical Sciences, Ahvaz, Iran.
Full name of responsible person
Dr Nader Saki
Street address
Golestan Highway, Ahvaz Jondishapoor University of Medical Sciences, Ahvaz, Iran.
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jondishapoor University of Medical Sciences, Ahvaz, Iran.
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*

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Full name of responsible person

Mehnoosh Samadi

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City**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*