Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of calorie restricted diet adjunctive with green coffee been extract supplementationonsome metabolic factors, anthropometric measures, plasma free fatty acids, visceral fat indiceand 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 indiceand 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

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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 supplementationonsome 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 inflamation
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

Person responsible for general inquiries

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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