Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of olive leaf extract on weight and body composition, free fatty acid, glycemic factors, lipid profile and serum level of adipocytokines in obese women on a weight-loss diet

Protocol summary

Study aim

Determine the effect of olive leaf extract on weight and body composition, free fatty acid, glycemic factors, lipid profile and serum level of adipocytokines in obese women on a weight-loss diet

Design

This is a double-blind, parallel-group, randomized controlled clinical trial

Settings and conduct

This study will be carried out by referring to private nutrition office in Ahvaz city. Individuals in the intervention and control group will receive 250 mg of olive leaf extract daily in the form of pills or placebo for 2 months, respectively. Each person will fill the individual consent, physical activity and food record questionnaires. At the beginning and the end of the study, fasting blood samples are taken from 5 mL blood donors. energy needs will calculate by Mifflin Jeor St equation. Then, 500 kcal of estimated energy requirements will deduct.

Participants/Inclusion and exclusion criteria

Eligibility criteria: women aged 18 to 50 years old and body mass index (BMI) between 30 to 40; Non eligibility criteria: menopause, pregnancy and breastfeeding, having history of food allergy, cancer, acute or chronic renal failure, acute or chronic hepatic failure, thyroid disorder and gastrointestinal diseases, having surgical operation for weight loss, having weight loss over the past six months ,consumption of multivitamin/mineral or herbal supplements and weight-loss drugs, did not use of more than 10% of drugs

Intervention groups

1) Placebo group plus a standard hypocaloric diet 2) Olive leaf extract supplementation group plus a standard hypo-caloric diet

Main outcome variables

Weight, body composition, free fatty acid level, glycemic status, lipid profile, leptin, adiponectine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190129042552N2**
Registration date: **2020-05-30, 1399/03/10**
Registration timing: **prospective**

Last update: **2020-05-30, 1399/03/10**
Update count: **0**

Registration date

2020-05-30, 1399/03/10

Registrant information

Name

Forough Shayesteh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3376 5113

Email address

forough_shayesteh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of olive leaf extract on weight and body composition, free fatty acid, glycemic factors, lipid profile and serum level of adipocytokines in obese women on a weight-loss diet

Public title
Evaluation of olive leaf extract in obese women on weight-loss diet

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18-50 years Body mass index 30-40 kg/m2

Exclusion criteria:
Menopause Pregnancy and breast feeding Food allergy Having a history of cancer, acute or chronic renal Failure, acute or chronic hepatic failure, thyroid disorder and gastrointestinal diseases Having surgical operation to weight loss Having weight loss over the past six months Consumption of multivitamin/mineral supplements, herbal supplements or weight-loss drugs Don’t use more than 10% of medications

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible subjects will be divided randomly into two groups including control and intervention. Randomization will be performed using the computer-generated random numbers. the naming of olive leaf extract or placebo bottles will be done based on random numbers and odd or even numbers will be allocated to the A or B group. To achieve allocation concealment, the bottles will be sealed and we will be assured from the similarity of appearance and their weight. The randomization process will be performed by an individual other than the investigators to reduce the probable bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be done in the case of participants and the main investigator. For blinding, placebo capsules will be prepared in the same size, shape, bottle with olive leaf extract capsules. Bottles will be encoded A or B. Also, the researcher is unaware of the type of capsules. Therefore, that participants and researcher will be blinded at the selection step and information collection.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan Blvd

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2020-05-02, 1399/02/13

Ethics committee reference number
IR.AJUMS.REC.1399.146

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Body weight

Timepoint
Before, after 4 and 8 weeks

Method of measurement
Scale

2

Description
Body composition

Timepoint
Before, 4 weeks and 8 weeks after intervention

Method of measurement
Bioelectrical impedance analysis

3

Description
Serum level of free fatty acid
Timepoint
Before and 8 weeks after intervention
Method of measurement
ELISA

4

Description
Fasting blood sugar (FBS)
Timepoint
Before and 8 months after intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

5

Description
Homeostatic Model Assessment for Insulin Resistance (HOMA-IR)
Timepoint
Before and 8 months after intervention
Method of measurement
HOMA-IR: [fasting insulin Mu/ml × fasting glucose mg/dl]/405

6

Description
Lipid profile
Timepoint
Before and 8 months after intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

7

Description
Serum level of leptin
Timepoint
Before and 8 weeks after intervention
Method of measurement
ELISA

8

Description
Serum level of adiponectin
Timepoint
Before and 8 weeks after intervention
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily intake of 250 mg olive leaf extract as 2 pills and weight loss diet
Category
Treatment - Drugs

2

Description
Control group: Daily intake of 250 mg placebo as 2 pills and weight loss diet
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr.Majid Mohammadshahi s Diet Therapy Office
Full name of responsible person
Forough Shayesteh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
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

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Shayesteh
Position
PhD student of nutrition sciences
Latest degree
Master
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not 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
Title and more details about the data/document
Publication of protocol study in form of the article and also data publication in the original article. The total potential data can be shared after unidentifiable

subjects.

When the data will become available and for how long

6 months after the publication of results

To whom data/document is available

All researchers who have access to clinical trials databases

Under which criteria data/document could be used

The only way for using the data is after the publication of the article in the indexed ISI journal.

From where data/document is obtainable

Via database websites such as PubMed and google scholar and via email address: forough_shayesteh@yahoo.com

What processes are involved for a request to access data/document

The original article reaches the request or by email within a maximum of one week.

Comments