Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of dietary flaxseed and placebo on serum adiponectin, leptin, lipid profile and anthropometric indices among overweight or obese women: a clinical trial

Protocol summary

Summary

This study has been done in the form of randomized clinical trial with two parallel groups , in order to investigate the Effect of dietary flaxseed on adiponectin , leptin, lipid profile and anthropometric indices in overweight or obese women. Inclusion criteria: women between 20-50 years old; body mass index over 25 kg and less than 40 kg. Exclusion criteria: taking any medication or supplements that affect fat metabolism in the body and affect weight loss during last 3 months; history of allergy to flax seed; clinical diagnosis of kidney dysfunction, liver, heart, thyroid; history of cardiovascular disease, cancer, diabetes, gastrointestinal disorders that affect absorbtion; pregnancy; lactation; not willingness to cooperate. Individuals are invited to participate in the study through public invitation (published in the newspaper or some organization under observation of Shiraz University of Medical Sciences). After that, individuals are assigned randomly into two groups of weight loss diet with 25 g / day of milled dietary flax seed or weight loss diet with 25 g / day raw rice flour for 12 weeks. Randomization is done through bock randomization method. Required energy intake per day calculated for each participant through Estimated Energy Requirement formula (EER) and we will subtract 500 kcal of the amount we calculated. Follow up will be done in 0, 4, 8, 12 weeks. In the first visit (week 0), baseline data is collected and patients will receive milled flax seed powder or raw rice flour for 4 weeks. In each follow up session, patients will receive sufficient quantities of milled flax seed powder or raw rice flour. Adherence to study protocol will be checked by asking participant to bring back the amounts of powder that they haven’t use and these amounts will be weighed and values will be recorded in each follow up. Participant in each group will be recommended to add powder into yogurt and use them half an hour before lunch. Anthropometric measurements (height, weight, waist circumference, hip circumference) will be done for each participant at baseline (0 week) and at the end of the study (12 week) .The blood sampling is done in order to measure biochemical parameters, including lipid profile (total cholesterol, LDL-c, HDL-c, triglycerides) and neuro hormonal systems (leptin and adiponectin) at the beginning and at the end of the study. For all participants 24-hour dietary recall for 3 days including a holiday and two business days will be completed through interviewing or telephone call, at the beginning and at the end of the twelfth week. Physical activity levels are calculated by using two working days and a holiday at the beginning and at the end of week 12. Clinical, laboratory and food intake indices are evaluated at the beginning and at the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050327733N1**
Registration date: **2017-02-08, 1395/11/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-08, 1395/11/20

Registrant information

Name

Hoda Ahmadniay Motlagh

Name of organization / entity

School of Nutrition and Food Sciences

Country

Iran (Islamic Republic of)

Phone

+98 37251001

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research,Shiraz University of Medical Sciences

Expected recruitment start date
2016-04-20, 1395/02/01
Expected recruitment end date
2016-05-21, 1395/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of dietary flaxseed and placebo on serum adiponectin, leptin, lipid profile and anthropometric indices among overweight or obese women: a clinical trial

Public title
The effect of dietary flaxseed on Obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: women between 20-50 years old; body mass index over 25 kg and less than 40 kg, he no history of alcohol abuse or using alcohol less than 10 mg per day for women and less than 20 mg per day in men.
Exclusion criteria: taking any medication or supplements that affect fat metabolism in the body and affect weight loss during last 3 months; history of allergy to flax seed; clinical diagnosis of kidney dysfunction, liver, heart, thyroid; history of cardiovascular disease, cancer, diabetes, gastrointestinal disorders that affect absorbtion; pregnancy; lactation; not willingness to cooperate.
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Ethics committee of Shiraz University of Medical Science
Street address
Center building of Shiraz University of Medical Sciences , infront of felestin street, zand avenue, Shiraz
City
Shiraz
Postal code
14336 71348
Approval date
2016-07-10, 1395/04/20
Ethics committee reference number
IR.SUMS.REC.1395.22

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
Low density lipoprotein
Timepoint
At the beginning of study and 12th week of study
Method of measurement
Auto analysis mashine and calroimetry method

2

Description
Weight
Timepoint
At the beginning of study after 8 week and at the end of intervention
Method of measurement
Tape measurment,scale

3

Description
Height
Timepoint
At the beginning of study
Method of measurement
Tape measurement scale

4

Description
Adiponectin
Timepoint
At the beginning of study and 12 weeks after intervention
Method of measurement
ELISA method

5

Description
leptin
Timepoint
At the beginning of study and 12th week of study
Method of measurement
ELISA method

6

Description
Triglycerid
Timepoint
At the beginng and 12th week after intervention
Method of measurement
Auto analyser device and Calorimetriy method

7

Description
Total cholesterol
Timepoint
At the beginng and 12th week after intervention
Method of measurement
Auto analyser device and Calorimetriy method

8

Description
High density lipoprotein
Timepoint
At the beginng and 12th week after intervention
Method of measurement
Auto analyser device and Calorimetriy method

9

Description
Waist circumference
Timepoint
At the beginning and end of study
Method of measurement
Tape measurement scale

10

Description
Hip circumference
Timepoint
At the beginning and end of study
Method of measurement
Tape measurement scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They will use 25g/day milled brown flaxseed in addition to weight loss diet for 12 weeks
Category
Placebo

2

Description
Control group: They will use 25g/day raw rice flour in addition to weight loss diet for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Public Health Center
Full name of responsible person
Hoda Ahmadniay Motlagh
Street address
Ghaani street, Moshir crossroad
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Doctor seyed Masum Masumpoor
Street address
Centeral buliding of Shiraz University of Medical Sciences, in front of Felestin avenue, Zand street
City
Shiraz
Grant name
-

Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shiraz University of Medical Sciences
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

Contact
Name of organization / entity
School of Nutrition and Food Sciences of Shiraz
Full name of responsible person
Hoda Ahmadniay Motlagh
Position
Master student
Other areas of specialty/work
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Person responsible for scientific 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