Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 2026

Effect of whey protein on levels of endocannabinoids, glycemic and lipid profile, inflammatory factors, adipocytokines and body composition in obese women on a weight-loss diet

Protocol summary

Summary

This is a clinical trial with the goal of determine the effect of whey protein on levels of endocannabinoids, glycemic and lipid profile, inflammatory factors, adipocytokines and body composition in premenopausal obese women on a weight-loss diet. Inclusion criteria include aged 18 years and older; BMI range of 30 to 40 kg/m2; absence of menopause; lactation; pregnancy; food allergies; not having cancer, hepatic, renal, thyroid and gastrointestinal disorders; no surgery for weight loss; no weight loss over the past 6 months; no taking herbs and drug that reduce appetite and weight and vitamin-mineral supplements and exclusion criteria is become pregnant during study; unwilling to continue; no consumption of powders exceed 10% of total administered powders. Eligible subjects will be stratified according to age and BMI randomly assigned to one of two groups: control (standard weight loss group, n=30) and intervention (whey supplementation weight loss group, n=30). Each of intervention group subjects, will receive 30grams whey protein powders per day. Each subject will be interviewed with a questionnaire to collect demographic, physical activity and 24 hr recall information. At baseline and end of trial, 10ml of venous blood samples will be collected after overnight fasting. All participants will follow a hypo-caloric diet of 800 kcal below estimated energy requirements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021410181N8**
Registration date: **2017-03-10, 1395/12/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-10, 1395/12/20

Registrant information

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Fatemeh Heidari
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Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of whey protein on levels of endocannabinoids, glycemic and lipid profile, inflammatory factors, adipocytokines and body composition in obese women on a weight-loss diet

Public title

Effect of whey protein on weight loss

Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria : aged 18 years and older; BMI range of 30 to 40 kg/m2; absence of menopause; lactation; pregnancy; food allergies; not having cancer, hepatic, renal, thyroid and gastrointestinal disorders; no surgery for weight loss; no weight loss over the past 6 months; no taking herbs and drug that reduce appetite and weight and vitamin-mineral supplements. Exclusion criteria: become pregnant during study; unwilling to continue; no consumption of powders exceed 10% of total administered powders.
Age
From **18 years** old to **48 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz-Gholestan
City
Ahvaz
Postal code
15794-61357
Approval date
2017-02-07, 1395/11/19
Ethics committee reference number
ir.ajums.REC.1395.729

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
Serum Insulin
Timepoint
Before and 2 months after the intervention
Method of measurement
Bloodletting

2

Description
Endocannabinoids
Timepoint
Before and 2 months after the intervention
Method of measurement
Bloodletting

3

Description
Glucose
Timepoint
Before and 2 months after the intervention
Method of measurement
Bloodletting

4

Description
Leptin
Timepoint
Before and 2 months after the intervention
Method of measurement
Bloodletting

5

Description
Interluekin-6
Timepoint
Before and 2 months after the intervention
Method of measurement
Bloodletting

6

Description
Adiponectin
Timepoint
Before and 2 months after the intervention
Method of measurement

Bloodletting

7

Description
TNF-α
Timepoint
Before and 2 months after the intervention
Method of measurement
Bloodletting

8

Description
Lipid profile
Timepoint
Before and 2 months after the intervention
Method of measurement
Bloodletting

9

Description
Weight
Timepoint
Before and 2 months after the intervention
Method of measurement
Seca scale-kg

10

Description
Body Composition
Timepoint
Before and 2 months after the intervention
Method of measurement
Body Composition Analyzer

Secondary outcomes

empty

Intervention groups

1

Description
control group: will receive standard weight loss (macronutrients percent will be carbohydrate55%, fat 30% and 15% protein).
Category
Treatment - Other

2

Description
intervention group: Isocaleric weight loss diet and whey protein powders will be prescribed. Each of intervention group subjects, will receive 30 gram whey protein powders per day.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr.Majid Mohammadshahi,s Diet Therapy Clinic
Full name of responsible person
Vahideh Aghamohammadi
Street address
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Makhmalzadeh
Street address
Gholestan highway.Ahvaz
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Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur 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
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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