

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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

Name

Fatemeh Heidari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8255

Email address

haidari-f@ajums.ac.ir

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

Interleukin-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: Isocaloric 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

City

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Vahideh Aghamohammadi

Position

Phd Candidate of Nutrition Sciences

Other areas of specialty/work

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Vahideh Aghamohammadi

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Web page address**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