

# 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/m<sup>2</sup>; 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/m<sup>2</sup>; 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- $\alpha$

**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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*