

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Evaluation of milk protein concentrate (MPC) on serum levels of glucose, lipid profile, insulin, adipocytokines and body composition in obese women on a weight-loss diet

#### Protocol summary

##### Study aim

This is a clinical trial with the goal of determine the Evaluation of milk protein concentrate (MPC) on serum levels of glucose, lipid profile, insulin, adipocytokines and body composition in obese women on a weight-loss diet.

##### Design

Each of intervention group subjects, will receive 30grams milk protein concentration (MPC) powders per day for 2 months. 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.

##### Settings and conduct

obese women referred to Diet therapy clinic of Abadan Imam Khomeini Hospital will intake 30gr MPC powder supplement per day for 2 months.

##### Participants/Inclusion and exclusion criteria

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 eating disorders, particularly binge eating disorder (BED), bulimia, 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; changes in diet during the study period, no consumption of powders exceed 10% of total administered powders.

##### Intervention groups

Eligible subjects will be stratified according to age and BMI randomly assigned to one of two groups: control (standard weight loss group, n=22) and intervention (milk protein concentration (MPC) supplementation

weight loss group, n=22).

##### Main outcome variables

serum levels of glucose, lipid profile, insulin, adipocytokines and body composition

#### General information

##### Reason for update

changing the time of the intervention

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201223049804N1**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **prospective**

Last update: **2022-08-15, 1401/05/24**

Update count: **1**

##### Registration date

2021-01-10, 1399/10/21

##### Registrant information

###### Name

Mahsa Elahikhah

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5322 7942

###### Email address

mahsa.elahikhah@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-03, 1401/01/14

##### Expected recruitment end date

2022-09-05, 1401/06/14

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of milk protein concentrate (MPC) on serum levels of glucose, lipid profile, insulin, adipocytokines and body composition in obese women on a weight-loss diet

**Public title**

Evaluation of milk protein concentrate (MPC) on weight-loss

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

aged 18 years and older female BMI range of 30 to 40 kg/m<sup>2</sup> absence of menopause, lactation and pregnancy food allergies not having eating disorders, particularly binge eating disorder (BED), bulimia 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 changes in diet during the study period 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: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The subjects will be randomly stratified according to age and BMI using a permuted block randomization procedure by Random Allocation Software (RAS). They will be assigned to one of the two study groups: (1) Standard weight loss group (n=22) (control group) (2) MPC supplementation weight loss group (n=22) (intervention group)

**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

**Province**

Khouzestan

**Postal code**

15794-61357

**Approval date**

2021-01-03, 1399/10/14

**Ethics committee reference number**

IR.AJUMS.REC.1399.795

**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**

Leptin

**Timepoint**

Before and 2 months after the intervention

**Method of measurement**

Bloodletting

**2****Description**

Adiponectin

**Timepoint**

Before and 2 months after the intervention

**Method of measurement**

Bloodletting

**3****Description**

Body Composition

**Timepoint**

Before and 2 months after the intervention

**Method of measurement**

Body Composition Analyzer

#### 4

##### **Description**

Waist circumference

##### **Timepoint**

Before and 2 months after the intervention

##### **Method of measurement**

Tape measure

#### 5

##### **Description**

Body Mass Index

##### **Timepoint**

Before and 2 months after the intervention

##### **Method of measurement**

calculated as body weight(kg)divided by the height in meters square

## **Secondary outcomes**

#### 1

##### **Description**

Fasting Blood Sugar

##### **Timepoint**

Before and 2 months after the intervention

##### **Method of measurement**

Bloodletting

#### 2

##### **Description**

Lipid Profile

##### **Timepoint**

Before and 2 months after the intervention

##### **Method of measurement**

Bloodletting

#### 3

##### **Description**

Fasting Plasma Insulin

##### **Timepoint**

Before and 2 months after the intervention

##### **Method of measurement**

Bloodletting

#### 4

##### **Description**

Homeostasis Model Assessment of Insulin Resistance (HOMA-IR)

##### **Timepoint**

Before and 2 months after the intervention

##### **Method of measurement**

Bloodletting

#### 5

##### **Description**

Appetite

##### **Timepoint**

Before and 2 months after the intervention

##### **Method of measurement**

Questionnaire

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Isocaloric weight loss diet and milk protein concentration (MPC) powders will be prescribed. Each of intervention group subjects, will receive 30 gram milk protein concentration (MPC) powders per day.

##### **Category**

Treatment - Other

#### 2

##### **Description**

Control group: will receive standard weight loss (macronutrients percent will be carbohydrate55%, fat 30% and 15% protein).

##### **Category**

Treatment - Other

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Diet Therapy Clinic of Abadan Imam Khomeini hospital

###### **Full name of responsible person**

Mahsa Elahikhah

###### **Street address**

Shahid Montazeri

###### **City**

Abadan

###### **Province**

Khuzestan

###### **Postal code**

63168481111

###### **Phone**

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###### **Email**

mahsa.elahikhah@gmail.com

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Ahvaz University of Medical Sciences

###### **Full name of responsible person**

Dr.Mahdi Ahmadi Moghadam

###### **Street address**

Gholestan highway.Ahvaz

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ahmadi-m@ajums.ac.ir  
**Grant name**  
nrc-9912  
**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**  
Mahsa Elahikhah  
**Position**  
M.Sc student of Nutrition Science  
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Bachelor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be a plan to make this available  
**Statistical Analysis Plan**  
Undecided - It is not yet known if there will be a plan to make this available  
**Informed Consent Form**  
Undecided - It is not yet known if there will be 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