# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Effect of milk protein concentrates (MPC) on serum levels of Orexin-A, Apelin, and TNF- α 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 Orexin-A, Apelin, and TNF- α 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 reffered 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/m2; 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 Orexin-A, Apelin and TNF- α

## General information

**Reason for update**

changing the time of the intervention

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201223049804N2**
Registration date: **2021-04-07, 1400/01/18**
Registration timing: **prospective**

Last update: **2022-08-14, 1401/05/23**
Update count: **1**

**Registration date**

2021-04-07, 1400/01/18

**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**

2022-04-10, 1401/01/21

**Expected recruitment end date**

2022-09-11, 1401/06/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Effect of milk protein concentrates (MPC) on serum levels of Orexin-A, Apelin, and TNF- α 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/m2 absence of menopause, lactation and pregnancy no 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**
2021-02-27, 1399/12/09

**Ethics committee reference number**
IR.AJUMS.REC.1399.924

## 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**
Orexin-A

**Timepoint**
Before and 2 months after the intervention

**Method of measurement**
Bloodletting

### 2

**Description**
Apelin

**Timepoint**
Before and 2 months after the intervention

**Method of measurement**
Bloodletting

### 3

**Description**
TNF-α

**Timepoint**
Before and 2 months after the intervention

**Method of measurement**
Bloodletting

**4**

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

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Isocaleric 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**
Khouzestan
**Postal code**
63168481111
**Phone**
+98 61 5322 2443
**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
**City**
ahvaz
**Province**
Khouzestan
**Postal code**
1579461357
**Phone**
+98 61 3333 9092
**Email**
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
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nutrition
**Street address**
Golestan highway,ahvaz
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
1579461357
**Phone**
+98 61 3333 9092
**Email**
mahsa.elahikhah@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Dr. Haidari Fatemeh

**Position**
Nutrition Sciences Phd

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nutrition

**Street address**
Golestan highway,ahvaz

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
1579461357

**Phone**
+98 61 3333 9092

**Email**
haidari-f@ajums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Mahsa Elahikhah

**Position**
M.Sc student of Nutrition Science

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nutrition

**Street address**
Golestan highway,Ahvaz

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
1579461357

**Phone**
+98 61 3333 9092

**Email**
mahsa.elahikhah@gmail.com

## 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