

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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 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/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

Khuzestan

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: 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

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Abadan

Province

Khuzestan

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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

City

ahvaz

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Khuzestan

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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

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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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

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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

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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