

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Exploring the effect of high consumption of dairy products in a high-protein diet combined with aerobic exercise and calorie restriction on weight loss and central obesity reduction in overweight women

Protocol summary

Study aim

The study is a randomized clinical trial. The study aims to explore the effect of high consumption of dairy products in a high-protein diet combined with aerobic exercise and calorie restriction on weight loss and central obesity reduction in overweight women.

Design

A randomized intervention with 60 participants, with control group, parallel intervention groups with participants, blind evaluator

Settings and conduct

The study will be conducted at Imam Khomeini Hospital. The effect of a two-week diet with high protein and calcium restricted by 700 kcal per day combined with moderate intensity of aerobic exercise on weight loss and central obesity are measured and compared with a normal high-protein diet in similar conditions. The evaluator will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged between 20 and 45 years, no history of disease Exclusion criteria: Lactose intolerance and sensitivity to dairy protein, the presence of a metal device or heart pacemaker in the body, pregnancy, musculoskeletal problems and exercise-limiting neurological disorders that prevent the continuation of physical activity, weight-loss medications such as appetite suppressants, reluctance to cooperate

Intervention groups

Participants were randomly divided into the intervention group (the group on a high protein and dairy diet and a caloric intake restricted by 700 kcal, combined with moderate rate of aerobic exercise) and the control group (the group on a high protein and moderate dairy diet and a caloric intake restricted by 700 kcal daily, combined with moderate rate of aerobic exercise).

Main outcome variables

Waist circumference; abdominal and supra-iliac skin fold;

body fat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201102049229N1**

Registration date: **2020-12-19, 1399/09/29**

Registration timing: **prospective**

Last update: **2020-12-19, 1399/09/29**

Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name

zahra bodaghabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6119 2282

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploring the effect of high consumption of dairy products in a high-protein diet combined with aerobic exercise and calorie restriction on weight loss and central obesity reduction in overweight women

Public title

The effect of high consumption of dairy on women's weight loss

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Individuals with BMI between 25 and 29.9 Individuals aged between 20 and 45 years No history of disease (uncontrolled diabetes, severe cardiovascular disease, musculoskeletal limitations and exercise-limiting neurological disorders, uncontrolled blood pressure, chronic obstructive pulmonary disease, migraine, kidney disease, taking any medication that affects a person's weight, appetite, heart rate or ability to do physical exercise

Exclusion criteria:

Lactose intolerance and sensitivity to dairy protein The presence of a metal device or heart pacemaker in the body Pregnancy Musculoskeletal problems and exercise-limiting neurological disorders that prevent the continuation of physical activity Weight-loss medications such as appetite suppressants Reluctance to cooperate

Age

From **20 years** old to **45 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

Randomization based on a single sequence of random allocations is called simple randomization. In this study, simple randomization is used. Individuals are randomly assigned to one of the two study groups using the table of random numbers and receive the intervention of the same group. Accidental concealment will be conducted by a second person who does not participate in other stages of the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator of the results will be blind. The measurement and analysis, which are carried out two weeks after the diet, will be conducted by this person.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

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Central Building of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.

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1417653761

Approval date

2020-10-20, 1399/07/29

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.276

Health conditions studied**1****Description of health condition studied**

Overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Weight loss

Timepoint

At the beginning of the study and two weeks later

Method of measurement

Weight measurement by compartment body composition analyzer

2**Description**

Central obesity reduction

Timepoint

At the beginning of the study and two weeks later

Method of measurement

Measuring waist circumference, skin folds, and supra-iliac

Secondary outcomes

1

Description

Body composition

Timepoint

At the beginning of the study and two weeks after that

Method of measurement

Compartment body composition analyzer AVIS334

Intervention groups

1

Description

Intervention group: the group on a high-protein and high level of dairy diet and daily calorie restriction of 700 Kcal combined with medium intensity of aerobic exercise. For this group, a diet of high protein and calcium (1.5 grams of protein per kilogram of body weight) with dairy sources (milk-casein) and 700 kcal restriction per day is prescribed as needed. Moreover, aerobic exercise with medium intensity is prescribed (including jogging or running on treadmill 3 to 5 days a week for 2 weeks). Patients are given a logbook to record exercise, and a weekly food reminder is requested from the patient. After 2 weeks, the analysis is undertaken again.

Category

Prevention

2

Description

Control group: the group on a high-protein but moderate level of dairy diet and daily calorie restriction of 700 Kcal combined with medium intensity of aerobic exercise. Aerobic exercise with medium intensity is also prescribed for this group (including jogging or running on treadmill 3 to 5 days a week for 2 weeks). Patients are given a logbook to record exercise, and a weekly food reminder is requested from the patient. After 2 weeks, the analysis is undertaken again.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Zahra Alizadeh

Street address

Imam Khomeini Hospital, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hajar Moamai

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Alizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

No. 7, Sports Medicine Research Center, Opposite of

Shariati Hospital, Jalal Al-Ahmad Highway

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Person responsible for scientific inquiries

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Position

Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Yes - There is 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

No - There is not 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

Not applicable

Title and more details about the data/document

Initial results and other items at the request of researchers

When the data will become available and for how long

The period of access starts 6 months after the publication of results.

To whom data/document is available

Please contact this email: z_alizadeh@tums.ac.ir

Under which criteria data/document could be used

Please contact this email: z_alizadeh@tums.ac.ir

From where data/document is obtainable

Please contact this email: z_alizadeh@tums.ac.ir

What processes are involved for a request to access data/document

Please contact this email: z_alizadeh@tums.ac.ir

Comments