

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of high protein diet in regulating appetite, anthropometric indices, and body composition of Normal Weight Obese women

Protocol summary

Study aim

The aim of this study is to investigate the effect of high protein diet and standard protein on appetite status, body weight, body mass index (BMI), fat mass (FM) and lean body mass (LBM) in normal obese women.

Design

Design: In this randomized controlled trial, the participants randomly will be assigned to 2 groups. 25 women will be allocated in the control group to receive a diet regimen with a standard protein content (standard protein (SP); providing 0.8 g/kg body weight/day), and 25 women will be allocated in the intervention group to receive a diet regimen with a higher protein content (high protein (HP); providing 1.2 g/kg body weight/day) for 12 weeks. The diet regimens have an equal amount of calories in both groups according to the resting metabolic rate (BMR) based on the Harris-Benedict predictive formula.

Settings and conduct

The participants will not know whether they are a member of the HP group or the SP group.

Participants/Inclusion and exclusion criteria

Inclusion criteria into the study are for healthy women, aged between 30 to 60 years having a BMI (in kg/m²) <25 and >18.5, body fat >30 %. Exclusion criteria include: smoking, pregnancy, lactation, history or presence of kidney, gastrointestinal, liver, or thyroid disease, gout, certain cancers, or type 2 diabetes, severe weight changes within the last 3 months and bariatric surgery; recently following a high-protein diet or using anti-obesity medications or supplements; and consuming protein supplement and high amounts of caffeine (>250-300 mg/d).

Intervention groups

high protein diet and standard protein

Main outcome variables

The weight, body composition including fat body mass and lean body mass by BIA machine and appetite level by visual analogue scale questionnaire will be measured

before and after the trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170412033393N2**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **retrospective**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Neda Haghghat

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 705 0021

Email address

haghghat.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-05-21, 1397/02/31

Actual recruitment end date

2019-01-20, 1397/10/30

Trial completion date

2019-02-03, 1397/11/14

Scientific title

The effect of high protein diet in regulating appetite, anthropometric indices, and body composition of Normal Weight Obese women

Public title

High protein diet in normal weight obese women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

healthy women having a body mass index (kg/m²) <25 and >18.5 body fat>30 % aged between 30 to 60 years

Exclusion criteria:**Age**

From **30 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants divide into two groups randomly. Randomization will be carried out by means of a random number table; for this, an independent coordinator creates the randomization list assigning participants to the high protein diet group or standard protein diet 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**

Ethics committee of Ahvaz university of medical sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Ethics Committee

City

Ahvaz

Province

Khuzestan

Postal code

15794-61357

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.AJUMS.REC.1395.55

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

normal weight obesity

ICD-10 code

E66.8

ICD-10 code description

Other obesity

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

weight

Timepoint

6 months

Method of measurement

mechanical scale

2**Description**

Fat body mass

Timepoint

Before and after intervention

Method of measurement

BIA machine

3**Description**

Lean body mass

Timepoint

Before and after intervention

Method of measurement

BIA machine

Secondary outcomes**1****Description**

appetite score

Timepoint

before and after intervention

Method of measurement

Visual analogue scale questionnaire

Intervention groups

1

Description

Intervention group: high protein diet [high protein (HP); protein amount of 1.2 grams per kilogram body weight (gr/kg)]

Category

Lifestyle

2

Description

Control group: standard protein diet high protein diet [standard protein (SP); protein amount of 0.8 grams per kilogram body weight (gr/kg)]

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity clinic

Full name of responsible person

Meysam Alipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

Street address

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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

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

Neda Haghighat

Position

Ph.D of Nutrition Science

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable