

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Sep 2026

Effects of whey protein isolate long term consumption in comparison with soy protein isolate on appetite and calorie intake, anthropometric and metabolic indices, inflammatory and oxidative stress factors in healthy overweight and obese men

Protocol summary

Summary

(1) Objectives: Effects of whey protein isolate long term consumption in comparison with soy protein isolate on appetite and calorie intake, anthropometric and metabolic indices, inflammatory and oxidative stress factors in healthy overweight and obese men. (2) Design: Randomized, double blind, control without placebo, clinical trial phase 3 (3) Setting and Conduct: After the completing the written consent, the participants are randomized in to either the WPI (to intake 60 grams whey protein isolate) or SPI (to intake 60 grams soy protein isolate). In this study participants of each group intake the supplements solved in 500 ml water 30 minutes before lunch. Before and after the study demographic questionnaire, IPAC and 24 recall are filled out. Appetite, Calorie intake, blood pressure, anthropometric measurement, body composition and plasma Glucose, TC, VLDL, TG, LDL, HDL, Apolipoproteins a and b, HsCRP, MDA are measured. (4) Participants: 52 healthy overweight and obese men 30 to 65 years old. Inclusion Criteria: Healthy interested men between ages 30 to 65; BMI=25-40kg/m²; No usage of cigarette or drugs or alcohol; No usage of antioxidants; No usage of decreasing blood pressure drugs, decreasing blood lipids or decreasing blood glucose drugs; No usage of antioxidants, gain or lose weight supplements; No lose weight diets; No intake of high doses of caffeine during the last 3 months; No records of diabetes, high blood pressure, acute heart diseases or thyroid/kidney/liver diseases, blood disorders, infarction or other clinical problems increasing oxidative stress like injuries or sever burnings; No allergy to cow milk or soy; No sever weight change during the last month; No usage of drugs affecting body weight (Hormones or antidepressant drugs) Exclusion Criteria; Altering the activity levels or diets in comparison with the ones before the study;

Compliance less than 70% (5) Interventions: Intake of 60 grams of whey protein isolate or soy protein isolate (6) Main outcome measures: appetite, body weight, body composition

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109062365N3**

Registration date: **2012-02-21, 1390/12/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-02-21, 1390/12/02

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4734

Email address

vafa.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-04-03, 1391/01/15
Expected recruitment end date
 2012-06-04, 1391/03/15
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Effects of whey protein isolate long term consumption in comparison with soy protein isolate on appetite and calorie intake, anthropometric and metabolic indices, inflammatory and oxidative stress factors in healthy overweight and obese men

Public title
 Effects of whey protein isolate long term consumption in comparison with soy protein isolate on appetite and calorie intake, anthropometric and metabolic indices, inflammatory and oxidative stress factors in healthy overweight and obese men

Purpose
 Prevention

Inclusion/Exclusion criteria
 Inclusion Criteria: Healthy interested men between ages 30 to 65; BMI=25 to 40kg/m²; No usage of cigarette or drugs or alcohol; No usage of antioxidants; no usage of decreasing blood pressure drugs, decreasing blood lipids or decreasing blood glucose drugs; No usage of antioxidants, gain or lose weight supplements; No lose weight diets; No intake of high doses of caffeine during the last 3 months; No record of diabetes, high blood pressure, acute heart diseases or thyroid/kidney/liver diseases, blood disorders, infarction or other clinical problems increasing oxidative stress like injuries or severe burnings; No allergy to cow milk or soy; No severe weight change during the last month, No usage of drugs affecting body weight (Hormones or antidepressant drugs), Exclusion Criteria: Altering the activity levels or diets in comparison with the ones before the study; Compliance less than 70%

Age
 From **30 years** old to **65 years** old

Gender
 Male

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **52**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double 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 Tehran University of Medical Sciences, School of Public health

Street address

School of Public Health , No 52, Alvand Avenue, Arjantin Square

City

Tehran

Postal code

1516846514

Approval date

2012-01-16, 1390/10/26

Ethics committee reference number

90-03-27-13475-43649

Health conditions studied

1

Description of health condition studied

Obesity and Overweight

ICD-10 code

E65, E66, E6

ICD-10 code description

Obesity and other hyperalimentation

Primary outcomes

1

Description

Body composition

Timepoint

Before and at the end of the first, second and the third month of the intervention

Method of measurement

Body composition analysis device

2

Description

Body weight

Timepoint

Before and after the intervention and every two weeks

Method of measurement

Scale

3

Description

Appetite
Timepoint
Before and after the intervention and weekly reports
Method of measurement
Questionnaire

Secondary outcomes

1
Description
Blood pressure
Timepoint
Before and after the intervention and every two weeks
Method of measurement
Mercury Barometer

2
Description
Serum Lipids Profile
Timepoint
Before and after intervention
Method of measurement
Autoanalyzer

3
Description
MDA
Timepoint
Before and after the intervention
Method of measurement
Autoanalyzer

4
Description
HS CRP
Timepoint
Before and after the intervention
Method of measurement
Autoanalyzer

5
Description
Glucose
Timepoint
Before and after the intervention
Method of measurement
Autoanalyzer

Intervention groups

1
Description
Intervention Whey Protein Group: Whey Protein Isolate ,90%, 60 grams per day 30 minutes before lunch for 12 weeks
Category

Prevention

2
Description
Intervention Soy Protein Group: Soy Protein Isolate ,90%, 60 grams per day 30 minutes before lunch for 12 weeks
Category
Prevention

Recruitment centers

1
Recruitment center
Name of recruitment center
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Reza Vafa
Street address
School of Public Health, No 52, Alvand Avenue, Arjantin Square
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Central Building of Tehran University of Medical Sceinces, Keshavarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Vafa

Position

Associate Professor

Other areas of specialty/work**Street address**

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mrvafo@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Vafa

Position

Associate Professor

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty