

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 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%

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**

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

City

Tehran

Postal code**Phone**

+98 21 8877 9119

Fax**Email**

mrvafo@tums.ac.ir

Web page address**Email**

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

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

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

City

Tehran

Postal code**Phone**

+98 21 8877 9119

Fax**Email**

mrvafo@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Position

Associate Professor

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

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

City

Tehran

Postal code**Phone**

+98 21 8877 9118

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