

# 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/m<sup>2</sup>; 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/m<sup>2</sup>; 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**

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**Web page address**

## Person responsible for updating data

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## Person responsible for scientific inquiries

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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*