

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of dietary protein source on metabolic responses, appetite, and arterial stiffness indexes during the postprandial phase in overweight and obese men: A crossover study

#### Protocol summary

##### Study aim

Assessing the effect of dietary protein source (animal vs plant-based proteins) on metabolic responses, appetite, and arterial stiffness indexes during the postprandial phase in overweight and obese men

##### Design

Randomized crossover clinical trial, with two intervention groups, on 46 overweight and obese men. Randomization will be done using a random number table.

##### Settings and conduct

Interventions include two protein-based meals with different protein sources (animal and plant-based proteins). Each subject will complete two interventions on 2 different days with a washout period of one week between trials. On the test day, indirect calorimetry, Pulse Wave Velocity, subjective appetite, and venous blood will be measured in fasting state. After consuming test meals, the mentioned measurements will be done during 6 hours. This study will be conducted at Imam Reza Hospital of Mashhad, located in the northeast of Iran.

##### Participants/Inclusion and exclusion criteria

The Inclusion criteria are apparently healthy men between the age of 18 and 60 years old, BMI between 25 and 35 kg/m<sup>2</sup>. The exclusion criteria are professional athletes, being a current smoker, use of medications or supplements affecting energy and protein metabolism, appetite, and more than 10% change in body weight within the past 6 months.

##### Intervention groups

The two protein-based breakfast meals with different protein sources (animal or plant-based proteins). The test meals consist of 30% protein, 40% carbohydrate, and 30% fat. Each subject will complete two interventions with a one-week washout period between trials.

##### Main outcome variables

Thermic effect of the test meals, resting measurements of energy expenditure and substrate, appetite response, lipid profile, insulin, and blood glucose, as well as arterial stiffness indexes, including pulse wave velocity and augmentation index.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211230053570N1**

Registration date: **2022-02-10, 1400/11/21**

Registration timing: **prospective**

Last update: **2022-02-10, 1400/11/21**

Update count: **0**

##### Registration date

2022-02-10, 1400/11/21

##### Registrant information

##### Name

Zahra Dehnavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3734 6330

##### Email address

dehnaviz981@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2022-12-21, 1401/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of dietary protein source on metabolic responses, appetite, and arterial stiffness indexes during the postprandial phase in overweight and obese men: A crossover study

**Public title**

Postprandial effect of dietary protein source on metabolic responses

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men aged between 18 and 60 years old  
35 > BMI > 25  
Apparently healthy men  
Provision of written informed consent

**Exclusion criteria:**

Professional athletes  
Current smoking habits  
History of cardiovascular diseases, hypertension, diabetes mellitus, hyperlipidemia, neurological and/or neuropsychological disorders, and renal disorders  
Using medications or supplements affecting energy and protein metabolism (e.g., thyroid drugs, Supplements containing L-carnitine, ephedrine, caffeine, and antidepressant drugs)  
Using protein supplements  
Using weight loss or weight gain supplements  
Using medications or supplements affecting appetite  
History of more than 10% change in body weight within the past 6 months  
Skipping breakfast regularly (having breakfast less than 5 times a week)  
Having dietary restrictions  
Trypanophobia (extreme fear of injections, hypodermic needles) or haemophobia (extreme fear of blood)

**Age**

From **18 years** old to **60 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

As the present study is a crossover study, all of the two study groups will receive both interventions. In the present study, only the intervention initiation meal will be randomized. Participants will be randomly allocated to animal or plant-based protein groups based on a 1:1 ratio (simple randomization). The randomization will be performed using a random number table. A random sequence will be provided and included in envelopes by someone who is not a member of the research team. Each participant will randomly choose an envelope to be

allocated to one of the two test meal groups. As participants will consume both the protein meals, allocation concealment will not be done.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Nutrition Department, Medical School, Mashhad University of Medical Sciences, Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9343159878

**Approval date**

2021-04-20, 1400/01/31

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1400.399

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

Overweight and obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

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

Respiratory quotient

**Timepoint**

In the fasting state and during 5 hours after test meal (1, 3, and 5 hours after test meal)

**Method of measurement**

Indirect calorimetry (Metalyzer 3B)

## 2

### **Description**

Resting energy expenditure

### **Timepoint**

In the fasting state and during 5 hours after test meal  
(1,3, and 5 hours after test meal)

### **Method of measurement**

Indirect calorimetry (Metalyzer 3B)

## 3

### **Description**

Diet induced thermogenesis

### **Timepoint**

In the fasting state and during 5 hours after test meal  
(1,3, and 5 hours after test meal)

### **Method of measurement**

Indirect calorimetry (Metalyzer 3B)

## 4

### **Description**

Pulse wave velocity

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5 , and 5.5 hours after test meal)

### **Method of measurement**

Tonometry

## 5

### **Description**

Pulse wave analysis

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5 , and 5.5 hours after test meal)

### **Method of measurement**

Sphygmocor device

## 6

### **Description**

Appetite response

### **Timepoint**

In the fasting state and during 5 hours after test meal  
(every 1 hour)

### **Method of measurement**

Visual analogue scales (VAS)

## **Secondary outcomes**

## 1

### **Description**

Blood glucose level

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5, and 5.5 hours after test meal)

### **Method of measurement**

Enzymatic colorimetric method

## 2

### **Description**

Serum insulin level

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5, and 5.5 hours after test meal)

### **Method of measurement**

Elisa method

## 3

### **Description**

Triglyceride level

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5, and 5.5 hours after test meal)

### **Method of measurement**

Enzymatic method

## 4

### **Description**

Total cholesterol level

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5, and 5.5 hours after test meal)

### **Method of measurement**

Enzymatic method

## 5

### **Description**

Low Density Lipoprotein- cholesterol level

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5, and 5.5 hours after test meal)

### **Method of measurement**

Enzymatic method

## 6

### **Description**

High Density Lipoprotein-Cholesterol (HDL-C) level

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5, and 5.5 hours after test meal)

### **Method of measurement**

Enzymatic method

## 7

### **Description**

Serum free fatty acids

### **Timepoint**

In the fasting state and during 5.5 hours after test meal  
(0.5, 1.5, 3.5, and 5.5 hours after test meal)

### **Method of measurement**

Enzymatic Colorimetric

## **Intervention groups**

1

### Description

Intervention group: This group will receive an animal-based protein test meal. The test meal will provide 25% of the calculated total energy requirements and will consist of 30% protein (from animal sources), 40% carbohydrate, and 30% fat. This test meal consists of white bread, potatoes, sunflower oil, and egg, chicken, or yogurt (as the protein sources). The test meals will be prepared in the Nutrition Department kitchen at the Mashhad University of Medical Sciences, Mashhad, Iran. Chemical analysis will be performed on a sample of test meals to determine their macronutrient composition and amino acid profile.

### Category

Other

2

### Description

Intervention group: This group will receive a plant-based protein test meal. The test meal will provide 25% of the calculated total energy requirements and will consist of 30% protein (from plant sources), 40% carbohydrate, and 30% fat. This test meal will contain white bread, potatoes, sunflower oil, lentils, and soy (as the protein sources). The test meals will be prepared in the Nutrition Department kitchen at the Mashhad University of Medical Sciences, Mashhad, Iran. Chemical analysis will be performed on a sample of test meals to determine their macronutrient composition and amino acid profile.

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam reza hospital

#### Full name of responsible person

Mohammad Safarian

#### Street address

Nutrition Department, Medical School, Mashhad University of Medical Sciences, Azadi Square

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137673119

#### Phone

+98 51 3800 2420

#### Email

safarianm@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Majid Ghayour Mobarhan

#### Street address

Research assistant, Mashhad University of Medical Sciences, Daneshgah Avenue

#### City

Mashhad

#### Province

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#### Postal code

9137673119

#### Phone

+98 51 3800 2420

#### Email

GhayourM@mums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Zahra Dehnavi

#### Position

PhD student

#### Latest degree

Master

#### Other areas of specialty/work

Nutrition

#### Street address

Nutrition Department, Medical School, Mashhad University of Medical Sciences, Azadi Square

#### City

Mashhad

#### Province

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#### Postal code

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**Email**  
dehnaviz981@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Zahra Dehnavi  
**Position**  
PhD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Nutrition Department, Medical School, Mashhad  
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**Postal code**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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Zahra Dehnavi  
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PhD student  
**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Individually nonidentifiable data of participants will be shared in this study. also, the protocol, results, and statistical analysis of the study will be published in the relevant articles

### When the data will become available and for how long

Data will be available after the publication of the related articles (starting in 2023)

### To whom data/document is available

Unidentifiable personal data of the participants will be made available after to other researchers at academic institutions

### Under which criteria data/document could be used

Unidentifiable personal data of the participants can only be used for research

### From where data/document is obtainable

Individually nonidentifiable information of participants can be obtained by sending an email to Dr Mohammad Safarian( safarianm@mums.ac.ir)

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

Other researchers in academic institutions can send their requests by email to Dr. Mohammad Safarian. The data will be sent to them after consulting and approving the research team.

### Comments