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/m2. 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 indices, 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 Univercity 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
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safarianm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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