Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of the effectiveness of replacing animal-based proteins with plant-based proteins on adropin levels, atherogenic index of plasma, and metabolic syndrome components in subjects with metabolic syndrome.

Protocol summary

Study aim

Determining and comparing of the effectiveness of replacing animal-based proteins with plant-based proteins on adropin levels, atherogenic index of plasma, and metabolic syndrome components in subjects with metabolic syndrome

Design

A randomized parallel clinical trial with a control group on 66 people with metabolic syndrome. A valid site for creating random numbers (https://www.sealedenvelope.com/simple-randomiser/v1/lists) will be used for randomization.

Settings and conduct

Sixty-six people with metabolic syndrome will enter a randomized clinical trial after meeting the inclusion criteria. Participants will then be placed in one of two diet groups using balanced (permuted) block randomization method. The duration of the intervention will be 10 weeks. The first group will receive a diet containing 70% animal protein and 30% plant protein and the second group will receive a diet containing 30% animal protein and 70% plant protein. The percentage of macronutrients in both groups is considered the same.

Participants/Inclusion and exclusion criteria

Teachers aged 20 to 55 years old working in Isfahan with metabolic syndrome. Desire to participate in the study. Body mass index between 25 to 35 kg/m2. Lack of special diet for the past 6 months. Do not use dietary supplements. No history of kidney, liver, cardiovascular, thyroid or cancer diseases. Do not use hormonal drugs, birth control pills, glucocorticoids and drugs to lower blood sugar, blood pressure and lipids. Lack of pregnancy and lactation. No alcohol, cigarettes and tobacco.

Intervention groups

Control group: animal-based protein diet (containing 70% animal protein and 30% plant protein). Intervention group: plant-based protein diet (containing 30% animal protein and 70% plant protein).

Main outcome variables

Adropin; atherogenic index of plasma; metabolic syndrome components

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150909023957N10**
Registration date: **2022-05-16, 1401/02/26**
Registration timing: **prospective**

Last update: **2022-05-16, 1401/02/26**
Update count: **0**

Registration date

2022-05-16, 1401/02/26

Registrant information

Name

Sayyed Morteza Safavi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3168

Email address

safavimorteza@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01
Expected recruitment end date
2022-08-06, 1401/05/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of the effectiveness of replacing animal-based proteins with plant-based proteins on adropin levels, atherogenic index of plasma, and metabolic syndrome components in subjects with metabolic syndrome.

Public title
The effect of replacing animal-based proteins with plant-based proteins on metabolic syndrome treatment
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Desire to participate in the study Male and female teachers working in Isfahan Age 20 to 55 years and Iranian nationality Diagnosis of metabolic syndrome based on JIS criteria Body mass index between 25 to 35 kg/m2
Exclusion criteria:
Follow a special diet for the past 6 months Dietary supplements use History of kidney, liver, cardiovascular, thyroid and cancer diseases Use of hormonal drugs, birth control pills, glucocorticoids and drugs to lower blood sugar, blood pressure and lipids Pregnancy and lactation Alcohol, cigarettes and tobacco use
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be placed in one of two diet groups using balanced (permuted) block randomization method and using a valid site (https://www.se aledenvelope.com/simple-randomiser/v1/lists)for creating random numbers using quadratic blocks.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs -Medical University of Isfahan
Street address
Hezar jrib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-12-04, 1400/09/13
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.370

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Adropin
Timepoint
Initiation and end of the study (after 10 weeks)
Method of measurement
ELISA

2

Description
The atherogenic index of plasma (AIP)
Timepoint
Initiation and end of the study (after 10 weeks)
Method of measurement
Log (TG/HDL_C)

3

Description
Component of metabolic syndrome including fasting

blood sugar, lipid profile, waist circumference, and blood pressure

Timepoint
Initiation and end of the study (after 10 weeks)

Method of measurement
Fasting blood sugar and lipid profile by enzymatic method and auto-analyzer, waist circumference using tape measure and blood pressure using Omron Upper arm Blood Pressure

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Plant-based protein diet (diet containing 30% animal protein and 70% plant protein)

Category
Treatment - Other

2

Description
Control group: Animal-based protein diet (diet containing 70% animal protein and 30% plant protein)

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Schools of Isfahan

Full name of responsible person
sayyed Morteza Safavi

Street address
Hezar jrib

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 913 269 8847

Email
safavimorteza@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor in Research Affairs -Medical University of Isfahan

Full name of responsible person
Mansour Siavash Dastjerdi

Street address
Hezar jrib

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 7898

Email
research@mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Vice-Chancellor in Research Affairs -Medical University of Isfahan

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
Esfahan University of Medical Sciences

Full name of responsible person
Sayyed Morteza Safavi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Hezar jrib

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3168

Email
safavimorteza@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Sayyed Morteza Safavi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Hezar Jarib Avenue, Isfahan University of Medical Sciences, School of Nutrition and Food Science, Is

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3168

Fax
+98 31 3873 1866

Email
safavimorteza@nutr.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Farnaz Shahdadian

Position
Ph.D student

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
Hezar jrib

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 913 269 8847

Email
fshahdadian@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data of the main outcomes along with the method and materials and analysis as well as the informed consent can be shared after the hiding individuals.

When the data will become available and for how long
One year after the publication of the results

To whom data/document is available
Research centers and Vice-Chancellor in Research Affairs

Under which criteria data/document could be used
research use

From where data/document is obtainable
Dr. Sayyed Morteza Safavi

What processes are involved for a request to access data/document
Letter from the Vice-Chancellor in Research Affairs and the Ethics Committee

Comments