

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

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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.sealedenvelope.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

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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

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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

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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

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Person responsible for updating data

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Full name of responsible person

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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