

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of Time-Restricted Eating versus Standard Dietary Advice on Arterial Stiffness Indices in Men with Metabolic Syndrome

Protocol summary

Study aim

Determining the effect of time-restricted eating versus standard dietary advice on arterial stiffness indices in men with metabolic syndrome

Design

Clinical trial with control group, with parallel groups, without blinding, simple randomization, using sealed envelopes and random numbers with the help of RandoMaize.com, on 48 patients

Settings and conduct

A meal containing 500 kcal (50% carbohydrates, 20% protein and 30% fat) will be provided at the beginning and end of the study. Then, in the fasting state, 60 minutes later and 120 minutes later, the blood sample is taken. Weight, height, waist circumference, bioelectrical impedance analysis (BIA), complete blood count (CBC), liver function (ALT, AST), CRP, lipid profile, glucose, insulin, insulin resistance, blood pressure, Pulse Wave Velocity (PWV) and indirect calorimetry will be evaluated at the beginning of the study and after 6 weeks. In the third week, weight, blood pressure, lipid profile, glucose, insulin and insulin resistance will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men between the ages of 18 and 65, Body mass index (BMI) below 35, Specific work and sleep schedule, The duration of receiving daily food more than 14 hours, Diagnosis of metabolic syndrome according to the International Diabetes Federation (IDF) definition
Non-inclusion criteria: Diabetes, People being treated for hyperglycemia or hypercholesterolemia or hypertension, Thyroid disorders based on thyroid tests or thyroxine use, Eating disorders, Serious diseases that affect food intake such as cancer, Using supplements that contain compounds other than vitamins and minerals, Inability to follow time-restricted eating diet

Intervention groups

Intervention group: time-restricted diet (they will receive food in a 10-hour period.) Control group: diet without time restriction

Main outcome variables

Pulse Wave Velocity (PWV)

General information

Reason for update

Due to the prolongation of the patient screening process (according to the inclusion and exclusion criteria) and the failure of some required devices, the sampling starts with a delay.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201230049889N1**

Registration date: **2022-08-14, 1401/05/23**

Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**

Update count: **1**

Registration date

2022-08-14, 1401/05/23

Registrant information

Name

Aliyeh Ghannadzadeh Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Time-Restricted Eating versus Standard Dietary Advice on Arterial Stiffness Indices in Men with Metabolic Syndrome

Public title

The Effect of Time-Restricted Eating on Arterial Stiffness Indices in Patients with Metabolic Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Men between the ages of 18 and 65 Body mass index (BMI) below 35 Diagnosis of metabolic syndrome according to the International Diabetes Federation (IDF) definition Willingness to participate in the study by signing the informed consent form

Exclusion criteria:

Diabetes Thyroid disorders based on thyroid tests or thyroxine use Eating disorders Serious diseases that affect food intake, such as cancer Using supplements that contain compounds other than vitamins and minerals Inability to follow time-restricted eating diet Specific work and sleep schedule The duration of receiving daily food less than 14 hours

AgeFrom **18 years** old to **65 years** old**Gender**

Male

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **48****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method: simple Randomization Unit: Individual Randomization tool: sealed envelope (SNOSE: sequentially numbered, opaque, sealed envelopes) How to make a random sequence: Randomaize.com randomization site Explanation about allocation concealment: Random numbers are prepared with the help of Randomaize.com and printed and placed inside the envelope by a member of the research team. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then first, the purpose of the study is explained to the person who meets the listed conditions. If desired, the person signs the informed consent form and takes an envelope. Then opens it and based on the contents of the envelope, the person is entered in the intervention or control group.

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**

Ethics committee of Mashhad University of Medical Sciences

Street address

School of Medicine, Mashhad University of Medical Sciences, East door of Ferdowsi University, Azadi Sq.

City

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Razavi Khorasan

Postal code

9177948564

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.213

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

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

2**Description of health condition studied**

Arterial stiffness indices

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Time-restricted eating

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

Pulse wave velocity (PWV)

Timepoint

At the beginning of the study and after 6 weeks from the start of the study

Method of measurement

Pulse Wave Velocity device

Secondary outcomes

1

Description

Body weight

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

Scales

2

Description

Waist circumference

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Meter

3

Description

Body composition

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Bioelectric Impedance Analysis (BIA) device

4

Description

Complete blood count (CBC)

Timepoint

At the beginning of the study (fasting and 120 minutes after a meal) and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

5

Description

Alanine transaminase (ALT)

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

6

Description

Aspartate transaminase (AST)

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

7

Description

C-Reactive Protein (CRP)

Timepoint

At the beginning of the study (fasting and 120 minutes after a meal) and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

8

Description

Total cholesterol

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

9

Description

Triglyceride

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

10

Description

High-density lipoprotein (HDL)

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

11

Description

Low-density lipoprotein (LDL)

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

12

Description

Blood glucose

Timepoint

At the beginning of the study (fasting, 60 minutes after and 120 minutes after a meal) and 3 weeks and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

13**Description**

Insulin

Timepoint

At the beginning of the study (fasting, 60 minutes after and 120 minutes after a meal) and 3 weeks and 6 weeks after the start of the study

Method of measurement

Biochemical analysis of blood sample

14**Description**

Insulin resistance

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

Calculation of Homeostatic Model Assessment (HOMA)

15**Description**

Blood pressure

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

Sphygmomanometer

16**Description**

Metabolic rate

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Indirect calorimetry

17**Description**

Appetite status

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Visual Analog Scale (VAS)

18**Description**

Physical activity

Timepoint

3 days at the beginning of the study and 3 days at the end of the study

Method of measurement

Pedometer

19**Description**

Sleep status

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Pittsburg Questionnaire

20**Description**

Quality of life

Timepoint

At the beginning of the study and 6 weeks after the start of the study

Method of measurement

Short form of World Health Organization quality of life questionnaire (WHOQOL-BREF)

21**Description**

Dietary intake

Timepoint

At the beginning of the study and 3 weeks and 6 weeks after the start of the study

Method of measurement

3-day 24-hour recall

Intervention groups**1****Description**

Intervention group: In the intervention group, people will receive food in a period of 10 hours. It is recommended that this period be between 6 am and 8 pm. All foods and drinks except water, tea and coffee without added sweeteners should be consumed during this period. Due to not affecting the quality of sleep, tea and coffee consumption is allowed before 8 pm. With the help of researchers, participants will choose the best time frame that fits their life schedule. The patients' diet is according to their taste and freely, and there are no food restrictions. Participants will be explained about a healthy diet based on national dietary recommendations.

Category

Lifestyle

2**Description**

Control group: The control group will have a diet without time restriction and will receive the necessary recommendations about a healthy diet based on national dietary guidelines. In this group, the diet of the patients

is according to their taste and freely, and there are no food restrictions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Cohort center

Full name of responsible person

Mohsen Nemati

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Emam Reza Hospital, Emam Reza Sq.

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cohort@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/index.php/component/content/article/43-persian-category/1319-mums-persian-cohort/#visited>

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 of Mashhad University of Medical Sciences, Ghoreshi BLDG, in front of Daneshgah 18th, Daneshgah AVE

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Email

GhayourM@mums.ac.ir

Web page address

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

Aliyeh Ghannadzadeh Yazdi

Position

PhD Candidate

Latest degree

Medical doctor

Other areas of specialty/work

Nutrition

Street address

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GhannadzadehYA981@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Nemati

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

PhD Candidate

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Some collected data including the results of primary outcome measures will be presented.

When the data will become available and for how long

Access to data will be granted 6 months after publication.

To whom data/document is available

Data will be accessible for people working in academic institutions and people working in businesses upon request.

Under which criteria data/document could be used

Criteria for sharing deidentified data or other products will be evaluated based on case-by-case approach by the Mashhad University of Medical Sciences.

From where data/document is obtainable

Dr. Mohsen Nemati Address: Department of Nutrition, School of Medicine, Mashhad University of Medical Sciences, East door of Ferdowsi University, Azadi Sq., Mashhad Iran Post code: 9177948564 Email: NematyM@mums.ac.ir Phone number: 0098 51 38827034

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

Applicants should submit their detailed request through email. Their request will be evaluated by the researchers and the Mashhad University of Medical Sciences and will be available to the applicant if approved by the organization.

Comments