Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Sep 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
Age
From **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
Mashhad
Province
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
Pitssburg 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

Street address
Emam Reza Hospital, Emam Reza Sq.

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9137913316

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Email
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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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
Nutrition Department, School of Medicine, East door of Ferdowsi University, Azadi Sq.

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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

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Full name of responsible person
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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