Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of eight weeks combined training on the level of sirtuin1 and MicroRNA-122 in men with metabolic syndrome

Protocol summary

Study aim

Determining the effect of eight weeks of combined training on sirtuin 1 levels in men with metabolic syndrome Determining the effect of eight weeks of combined training on microRNA-122 in men with metabolic syndrome Determining the effect of eight weeks of combined training on FBS in men with metabolic syndrome Determining the effect of eight weeks of combined training on glycosylated hemoglobin in men with metabolic syndrome Determining the effect of eight weeks of combined training on the lipid profile of men with metabolic syndrome

Design

A clinical trial with the control group, with parallel, randomized groups, on 30 patients.Randomization by the method of equal blocks (8 blocks of 4) in which in each block half of the intervention and half of the people are considered as a comparison

Settings and conduct

Patients with metabolic syndrome in Imam Hossein (AS) Malayer Hospital

Participants/Inclusion and exclusion criteria

30 men aged 45-65 years (selected. These people had high blood pressure (more than 90/140 mm Hg), triglyceride levels above 150 mg / dL, fasting blood sugar above 120 mg/dl, and Obesity was also central. Then individuals were randomly divided into two groups of 15 combined exercise and control.

Intervention groups

Combined exercise group: which undergoes training intervention.

Main outcome variables

Combined training on sirtuin 1 and microRNA-122 levels in men with metabolic syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031921N1**
Registration date: **2022-05-30, 1401/03/09**
Registration timing: **prospective**

Last update: **2022-05-30, 1401/03/09**
Update count: **0**

Registration date

2022-05-30, 1401/03/09

Registrant information

Name

homa naderifar

Name of organization / entity

Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 6134

Email address

homa.naderifar@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-06, 1401/03/16

Expected recruitment end date

2022-12-07, 1401/09/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks combined training on the level of sirtuin1 and MicroRNA-122 in men with metabolic syndrome

Public title
The effect of combination exercises on metabolic syndrome
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Men with metabolic syndrome Age range between 45-65 years
Exclusion criteria:
Inability and inability to perform physical activity
Age
From **45 years** old to **65 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization is commonly used to balance the number of samples assigned to each of the intervention and comparison groups. This feature makes the number of samples assigned to each of the study groups equal in cases where intermediate analyzes are needed during the sampling process. In this randomization, the method of equal blocks (8 blocks of 4) is used in which in each block, half of the intervention subjects and half are considered as comparisons. And we assigned it to different groups. How and tool to generate random block sequences using the site https://www.sealedenvelope.com/simple-randomiser/v1/lists done.
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 University of Medical Scieneces
Street address
Mahdiyeh Ave
City
Hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۷۳۶
Approval date
2022-05-07, 1401/02/17
Ethics committee reference number
IR.UMSHA.REC.1401.145

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
Percentage of people who have decreased MicroRNA-122 levels
Timepoint
MicroRNA-122 measurement before and after the intervention
Method of measurement
Dedicated kit

2

Description
Percentage of people whose sirtuin levels have increased
Timepoint
measurement before and after the intervention
Method of measurement
Dedicated kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: training intervention. In the combined training group (resistance-aerobic) an 8-week aerobic program will include three training sessions per week and about one hour per day, which includes running on a treadmill. In this exercise program, subjects with 55% of maximum heart rate for 25 minutes (first 2 weeks), 55 to 65% of maximum heart rate for 35 minutes (second 2 weeks), 65 to 75% of maximum heart rate for 40 minutes Last 4 weeks) practiced. Before starting the exercise, the subjects warmed up for 10 minutes with soft and stretching movements, and at the end of the exercise, they cooled themselves for 10 minutes with

stretching movements. Also, the maximum heart rate was obtained through the age-220 formula. Comes and intensity of exercise was adjusted according to the desired percentage of maximum heart rate (Wilmore and Castiel, 1994). Resistance training with bodybuilding machines for 8 weeks and three sessions per week include: horizontal exercises, forearms, leg presses and Swedish swimming.

Category

Rehabilitation

2

Description

Control group: Which is not included in any training program

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein (AS) Hospital

Full name of responsible person

Saeid Shamloo Kazemi

Street address

Mahdiyeh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838678

Phone

+98 81 3838 0063

Email

hnaderifar121@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohi

Street address

Mahdiyeh Ave

City

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Postal code

6517838678

Phone

+98 81 3131 0000

Email

hnaderifar121@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Homa Naderifar

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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6517838678

Phone

0098813838063

Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

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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

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be sent to the researcher if the intellectual property rights are protected

From where data/document is obtainable

Email address

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

Submit a written application and complete the intellectual property form (one week)

Comments