Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of combined exercise (resistance exercise and high intensity interval training) versus control group on serum sirtuin 1 and 4 levels in men with non-alcoholic fatty liver disease: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of combined exercise (resistance exercise and high intensity interval training) versus control group on serum sirtuin 1 and 4 levels in men with non-alcoholic fatty liver disease

Design

This is a randomized clinical trial with a control group with parallel groups without blinding, in which 30 eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct

This study will be conducted at the Gymnasium at the Faculty of Sports Sciences, Bu-Ali Sina University in Hamadan city, involving 30 eligible patients with non-alcoholic fatty liver disease. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 50 years Non-alcoholic fatty liver grade 1 and 2 Exclusion criteria: Heart or respiratory disease Thyroid disorder Diabetes Muscle and joint disorders Smoking and alcohol use

Intervention groups

Intervention group: Training and routine recommendations plus combined resistance exercise and high-intensity interval training (HIIT) for 45 to 60 minutes, 3 days a week, for 12 weeks include: training at an intensity of 70% of heart rate reserve or 84% of maximum heart rate during sprints of up to 30 seconds, in the first 6 weeks with a 5-minute warm-up on a treadmill, then 4 sets of 3 minutes with 3 minutes of rest between sets, and in the second 6 weeks, 5 sets of 3 minutes with 3 minutes of rest between sets. Control group: Training and routine recommendations

Main outcome variables

Sirtuin 1 levels; Sirtuin 4 levels; Serum liver enzymes (ALT-AST); Serum lipid profile (LDL-HDL-CHOL-TG); Serum fasting blood glucose levels; Body mass index; Waist-hip ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N563**
Registration date: **2025-07-15, 1404/04/24**
Registration timing: **prospective**

Last update: **2025-07-15, 1404/04/24**
Update count: **0**

Registration date

2025-07-15, 1404/04/24

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-01, 1404/05/10

Expected recruitment end date

2025-09-01, 1404/06/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of combined exercise (resistance exercise and high intensity interval training) versus control group on serum sirtuin 1 and 4 levels in men with non-alcoholic fatty liver disease: a randomized clinical trial

Public title
Effect of combined exercise (resistance exercise and high intensity interval training) versus control group on serum sirtuin 1 and 4 levels in men with non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 50 years Non-alcoholic fatty liver grade 1 and 2
Exclusion criteria:
Heart or respiratory disease Thyroid disorder Diabetes Muscle and joint disorders Smoking and alcohol use
Age
From **18 years** old to **50 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
Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to 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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2025-02-15, 1403/11/27
Ethics committee reference number
IR.UMSHA.REC.1403.839

Health conditions studied

1

Description of health condition studied
Fatty liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Sirtuin 1 levels
Timepoint
Before intervention and 12 weeks later
Method of measurement
Using blood sampling

2

Description
Sirtuin 4 levels
Timepoint
Before intervention and 12 weeks later
Method of measurement
Using blood sampling

3

Description
Serum liver enzymes (ALT-AST)
Timepoint
Before intervention and 12 weeks later
Method of measurement
Using blood sampling

4

Description
Serum lipid profile (LDL-HDL-CHOL-TG)
Timepoint
Before intervention and 12 weeks later
Method of measurement
Using blood sampling

5

Description
Serum fasting blood glucose levels
Timepoint
Before intervention and 12 weeks later
Method of measurement
Using blood sampling

6

Description
Body mass index
Timepoint
Before intervention and 12 weeks later
Method of measurement
Using physical examination

7

Description
Waist-hip ratio
Timepoint
Before intervention and 12 weeks later
Method of measurement
Using physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training and routine recommendations plus combined resistance exercise and high-intensity interval training (HIIT) for 45 to 60 minutes, 3 days a week, for 12 weeks include: training at an intensity of 70% of heart rate reserve or 84% of maximum heart rate during sprints of up to 30 seconds, in the first 6 weeks with a 5-minute warm-up on a treadmill, then 4 sets of 3 minutes with 3 minutes of rest between sets, and in the second 6 weeks, 5 sets of 3 minutes with 3 minutes of rest between sets.
Category
Other

2

Description
Control group: Training and routine recommendations
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Gymnasium at the Faculty of Sports Sciences, Bu-Ali Sina University in Hamadan city
Full name of responsible person
Razieh Ghorbani Saber
Street address
Gymnasium at the Faculty of Sports Sciences, Bu-Ali Sina University, Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Alireza Soltanian
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info.research@umsha.ac.ir
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

Razieh Ghorbani Saber

Position

Physiology student

Latest degree

Master

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Physiologist

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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