

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of eight weeks of high intensity interval training (HIIT), resistance training and consumption of artichoke extract on the level of sirtuin 1 and team enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

Determining the effect of eight weeks of intense interval training (HIIT), resistance training and consumption of artichoke extract on the level of sirtuin 1 and liver enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in patients with non-alcoholic fatty liver disease.

Design

Clinical trial with control group, with parallel groups, randomized, on 60 patients. Randomization by the method of equal blocks (15 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

Settings and conduct

By referring to Hamedan Ba'ath Hospital, eligible people were identified and placed in the intervention groups using equal blocks randomization (15 blocks of 4). Then, people will go to the sports club for training intervention and perform exercises and supplements for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

Participants/Inclusion and exclusion criteria

Entry conditions: suffering from non-alcoholic fatty liver disease Conditions of non-entry: inability to practice

Intervention groups

Exercise and supplement group: In the exercise group, the samples are subjected to high-intensity and resistance intermittent exercises, and the supplement group consumes artichoke extract. The control group is not subjected to any intervention.

Main outcome variables

Non-alcoholic fatty liver, sirtuin 1, liver enzymes aspartate aminotransferase (AST) and alanine

aminotransferase (ALT)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056548N11**

Registration date: **2023-08-08, 1402/05/17**

Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**

Update count: **0**

Registration date

2023-08-08, 1402/05/17

Registrant information

Name

Saeid Shamlou kazemi

Name of organization / entity

Bu-Ali Sina university

Country

Iran (Islamic Republic of)

Phone

+98 912 859 7297

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saeidshamlou9092@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-08-16, 1402/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of high intensity interval training (HIIT), resistance training and consumption of artichoke extract on the level of sirtuin 1 and team enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in patients with non-alcoholic fatty liver disease

Public title

The effect of exercise and artichoke extract on non-alcoholic fatty liver

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Non-alcoholic fatty liver disease being menopausal

Exclusion criteria:

History of cardiovascular disease

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomization, the method of equal blocks (15 blocks of 4) has been used, in which a number of intervention people and a number of comparison people are included in each block, and we have allocated them to different groups. The method and tool of block random sequence generation has been done using <https://www.sealedenvelope.com/simple-randomiser/v1/lists>.

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 Sport Sciences Research Institute

Street address

Fifth Alley, Mir Emad Ave., Ostad Motahari Ave

City

Tehran

Province

Tehran

Postal code

1474674646

Approval date

2023-06-21, 1402/03/31

Ethics committee reference number

IR.SSRC.REC.1402.078

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

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

The percentage of people whose liver enzymes have decreased.

Timepoint

Before and after interventions

Method of measurement

By measuring the liver enzymes in the blood in the laboratory

Secondary outcomes**1****Description**

The percentage of people in whom the level of sirtuin 1 is increased.

Timepoint

Before and after interventions

Method of measurement

Using ELISA method and Zelbio kit made in Germany

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

Intervention group: Intense interval training was performed for 8 weeks and four sessions per week and

each session lasted for 60 minutes (15 minutes of warm-up + 30 minutes of interval training + 15 minutes of cooling) with an intensity of 80-85% of the maximum heart rate. They performed high-intensity resistance training of 7 movements 3 times a week. In the first two weeks, they did one maximum repetition and 6 repetitions with 90% intensity, in the third to fifth week with 95% maximum repetition and 4 repetitions, and the last three weeks with 100% ability and two repetitions. The amount of rest between sets was 1 minute and between stations was 2 to 3 minutes. For each subject in each station, which included barbell chest press, front shoulder with barbell, front underarm lat, front arm with cable hand, back arm with cable, front thigh with machine and back thigh with machine, the amount of weight It was found that it is usually able to lift less than 10 times. Artichoke extract is consumed in the following way. The parts of this plant were dried in the shade and crushed with the help of a grinder and turned into powder. The chopped leaves of the dried artichoke plant (fluffy silver leaves) were given to the study subjects in the form of packages in the required number, and they were asked to take them for 45 days, in two occasions (at night before going to bed; that is, two hours after eating dinner and the second time in the morning fasting one hour before breakfast) brew a tablespoon of plant leaves with a glass of boiling water for 20 minutes on indirect heat and at a temperature of 80 degrees Celsius.

Category

Treatment - Other

2

Description

Control group: This group is not subjected to any exercise intervention and supplement consumption.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Saeid Shamlou Kazemi

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6517838695

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saeidshamlou9092@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research at Danesh Alborz University

Full name of responsible person

Dr. Mohammad Tahernia

Street address

Danesh Alborz University, Abyek

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Qazvin

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6517838695

Phone

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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 President of Research at Danesh Alborz University

Proportion provided by this source

10

Public or private sector

Private

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

Bu-Ali Sina University

Full name of responsible person

Saeid Shamlou Kazemi

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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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 de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If the intellectual rights are preserved, the data can be sent to the researchers.

From where data/document is obtainable

Email address: saeidshamlou9092@gmail.com

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

Submission of a written request (one week)

Comments