

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effect of Eight Weeks Endurance Training and Low Calorie Diet on Serum Levels of Some Biomarkers Related to Endothelial Dysfunction-Atherosclerosis and Carotid Artery Carotid Intima Media Thickness in Men Involved Non-alcoholic Fatty Liver Disease

Protocol summary

Summary

The aim of this study was to investigate the effect of eight weeks endurance training and low calorie diet on some serum levels of biomarkers related to endothelial dysfunction-atherosclerosis and carotid intima media thickness in male patients involved nonalcoholic fatty liver disease. For this purpose, 32 Men involved non-alcoholic fatty liver disease selected and randomly will be divided into four groups, Endurance training (8 weeks of endurance training), either low calorie diet and endurance training groups (8 weeks of endurance training and diet), low-calorie diet group (8 weeks diet) and control group (without endurance training and diet). Before and after 8 weeks of intervention, carotid intima media thickness of all participants and serum levels of Lipid Profile, Homocysteine, hs-CRP, Visfatin, Pentraxin-3, Resistin and Chemerin of them will assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102330450N1**
Registration date: **2017-03-03, 1395/12/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-03, 1395/12/13

Registrant information

Name

Asgar Mahmoudi

Name of organization / entity

University of Mohaghegh Ardabili

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2016-11-05, 1395/08/15

Expected recruitment end date

2017-01-09, 1395/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Eight Weeks Endurance Training and Low Calorie Diet on Serum Levels of Some Biomarkers Related to Endothelial Dysfunction-Atherosclerosis and Carotid Artery Carotid Intima Media Thickness in Men Involved Non-alcoholic Fatty Liver Disease

Public title

The Effect of Exercise and Diet on Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Men with nonalcoholic fatty liver grade 2 and 3 detected by ultrasound; Do not use alcohol; Aged 18 to 45 years; The ability of doing physical

exercise. Exclusion criteria: Use of drug-induced hepatic steatosis such as prednisone, corticosterone, amiodarone and ...; uses more from 20 grams of alcohol daily; Hepatitis B and C.

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ardabil university of medical sciences

Street address

Ardabil- Kausar Town- Daneshgah Square- Ardabil
University of Medical Sciences

City

Ardabil

Postal code

5618985991

Approval date

2017-01-04, 1395/10/15

Ethics committee reference number

IR.ARUMS.REC.1395.93

Health conditions studied

1

Description of health condition studied

Nonalcoholic Fatty Liver Disease

ICD-10 code

k76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Visfatin

Timepoint

Before & aeter 8 weeks modality

Method of measurement

ELISA

2

Description

Resistin

Timepoint

Before & aeter 8 weeks modality

Method of measurement

ELISA

3

Description

hs-CRP

Timepoint

Before & aeter 8 weeks modality

Method of measurement

ELISA

4

Description

Lipid Profile

Timepoint

Before & aeter 8 weeks modality

Method of measurement

LDL,HDL.Chol,TG,VLDL

5

Description

Homocysteine

Timepoint

Before & aeter 8 weeks modality

Method of measurement

ELISA

6

Description

Chemerin

Timepoint

Before & aeter 8 weeks modality

Method of measurement

ELISA

7

Description

Carotid Intima Media Thickness

Timepoint

Before and aete 8 weeks modality

Method of measurement

Ultrasound

8

Description

Pentraxin-3

Timepoint

Before and after 8 weeks

Method of measurement

ELISA

Secondary outcomes

1

Description

ALT

Timepoint

Before & after 8 weeks

Method of measurement

ELISA

2

Description

AST

Timepoint

Before & after 8 weeks

Method of measurement

ELISA

3

Description

Body Mass Index

Timepoint

Before & after 8 weeks

Method of measurement

Weight and Height

4

Description

Malondialdehyde

Timepoint

Before & after 8 weeks

Method of measurement

ELISA

5

Description

Superoxide Dismutase

Timepoint

Before & after 8 weeks

Method of measurement

ELISA

6

Description

Glutathione Peroxidase

Timepoint

Before & after 8 weeks

Method of measurement

ELISA

7

Description

Total Antioxidant Capacity

Timepoint

Before & after 8 weeks

Method of measurement

ELISA

Intervention groups

1

Description

Endurance Exercise

Category

Lifestyle

2

Description

Endurance Exercise with Diet

Category

Lifestyle

3

Description

Diet

Category

Lifestyle

4

Description

Control Group, Without Lifestyle Modality

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Imam Khomeini Hospital

Full name of responsible person

Manuchehr Iranparvar

Street address

Ardabil Imam Khomeini Hospital

City

Ardabil

2

Recruitment center

Name of recruitment center

Ardabil Imam Khomeini Hospital

Full name of responsible person

Hassan Anari
Street address
Ardabil Imam Khomeini Hospital
City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Mohaghegh Ardabili
Full name of responsible person
Marefat Siahkohian
Street address
Ardabil-Daneshgah street- University of Mohaghegh
Ardabili
City
Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Mohaghegh Ardabili

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty