Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Asghar 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 aete 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 Gruop, 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

Name of organization / entity

University of Mohaghegh Ardabili

Full name of responsible person

Asghar Mahmoudi

Position

Ph.D. Candidate

Other areas of specialty/work

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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