Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of six weeks combined aerobic and resistance exercise training on some liver function parameters in Middle-aged men with non-alcoholic fatty liver disease.

Protocol summary

Summary
The purpose of this research is investigation of effect of six weeks combined aerobic and resistance training on some liver function parameters in Middle-aged men with non-alcoholic fatty liver disease. In this semi-experimental research, 16 Middle-aged men with non-alcoholic fatty liver disease randomly divide into two groups of exercise training and control. The exercise training program consisted of six weeks and three sessions per week combined of aerobic and resistance training. Body weight, BMI, blood levels of AST and ALT, Liver ultrasound, Vo2max, Waist-to-hip ratio, and body fat assessing at baseline and after six weeks. Data analyzing using analysis of covariance (ANCOVA) with dependent variable at baseline as covariate.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2017011821258N2**
Registration date: **2017-02-19, 1395/12/01**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2017-02-19, 1395/12/01

Registrant information
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Hojjatollah Siavoshy
Name of organization / entity
The University of Nahavand
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Recruitment status
Recruitment complete
Funding source
Islamic Azad University of Boroujerd

Expected recruitment start date
2014-12-31, 1393/10/10
Expected recruitment end date
2016-01-01, 1394/10/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of six weeks combined aerobic and resistance exercise training on some liver function parameters in Middle-aged men with non-alcoholic fatty liver disease.

Public title
Effects of exercise on nonalcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1. non-alcoholic fatty liver disease; 2. males; 3. having the age range of 45-30 years old. Exclusion criteria: 1. under the age of 30 years ; 2. age over 45 years old; 3. patients with cardiovascular disease; 4. patients with high blood pressure; 5. patients who have studied interoperability; 6. patients with musculoskeletal disorders; 7. people with Medical ban to participate in sports activities; 8. alcohol consumption.
Age
From **30 years** old to **45 years** old

Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **16**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamedan University of Medical Sciences and Health Services
Street address
Hamedan University of Medical Sciences and Health Services
City
Hamedan
Postal code
Approval date
2017-01-18, 1395/10/29
Ethics committee reference number
IR.UMSHA.REC.1395.466

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease (NAFLD)
ICD-10 code
K76.0
ICD-10 code description
Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes

1

Description
Blood Alanine Aminotransferase Enzyme (ALT)
Timepoint
Baseline and final (6th week)
Method of measurement
Blood samples test

2

Description
Blood Aspartate Aminotransferase Enzyme (AST)
Timepoint
Baseline and final (6th week)
Method of measurement
Blood samples test

3

Description
Liver fats
Timepoint
Baseline and final (6th week)
Method of measurement
Liver ultrasound

4

Description
Body weight
Timepoint
Baseline and final (6th week)
Method of measurement
Digital balance

5

Description
Body mass index
Timepoint
Baseline and final (6th week)
Method of measurement
Weight (kg) divided by square of height (m)

6

Description
Maximum oxygen uptake
Timepoint
Baseline and final (6th week)
Method of measurement
Rockport Fitness Walking Test

7

Description
Waist-to-hip ratio (WHR)
Timepoint
Baseline and final (6th week)
Method of measurement
Waist circumference divided by hip circumference

8

Description
Body fat percent
Timepoint
baseline and final (6th week)

Method of measurement
Measurement of skin fold thickness

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group participants performed six weeks and three sessions per week combined of aerobic and resistance training that Including: 60-90 minutes aerobic exercise With an intensity of 45-75% of maximum heart rate (At first, with 45 percent of maximum heart rate that gradually increased up to 75 percent of maximum heart rate) on the bike and elliptical trainer, and resistance training that Includes: 3 sets with 8-12 repetition, with 50% of one repetition maximum (At first, with 50 percent of one repetition maximum that gradually increased up to 75 percent of one repetition maximum) and bench press, squat, curl (to strengthen the both of upper and lower body), and knee extension.
Category
Lifestyle

2

Description
The control group participants continued with their usual activities, which may have included leisure and sporting activities but did not include a progressive resistance and aerobic training program.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Laboratories of Asadabad city in Hamadan Province
Full name of responsible person
Street address
Laboratories of Asadabad city in Hamadan Province
City
Asadabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University of Boroujerd
Full name of responsible person
Mohammad Ali Samavati Sharif
Street address
Islamic Azad University of Boroujerd
City
Boroujerd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University of Boroujerd
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
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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