Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of a training program on biochemical markers of non-alcoholic fatty liver

Protocol summary

Study aim
The effect of training on fatty liver
Design
One-line blind clinical trial with placebo
Settings and conduct
The statistical population of the present study is overweight and overweight women between the ages of 40-60 years old with non-alcoholic fatty liver in Astara. The participants in a full recall and notification to prenatal care, laboratories, pharmacies, health centers and with the participation of a number of general practitioners will be identified and then completed a demographic questionnaire, the patients who voluntarily wish to participate in research design They are required to enter the study. How to diagnose Fatty Liver Disease is that those who have been willing to participate in the research program should go to a documented clinic and visit it for free. Fasting, blood tests, and refer the result to the doctor. If the doctor is diagnosed and ultrasound is required to ensure the fat content of the liver, refer to the ultrasound center and refer the result to the doctor.
Participants/Inclusion and exclusion criteria
Age older than 40 Having fatty liver Not using any supplements Unwillingness to continue cooperation
Intervention groups
Exercise + Supplement placebo Practice Complementary
Main outcome variables
Cholesterol LDL HDL Tri glyceride ALT AST ALP BMI WHR fat percentage

General information

Reason for update
Acronym
کبد چرب غیرالکلی
IRCT registration information
IRCT registration number: **IRCT20190309042987N1**
Registration date: **2019-04-19, 1398/01/30**
Registration timing: **retrospective**
Last update: **2019-04-19, 1398/01/30**
Update count: **0**
Registration date
2019-04-19, 1398/01/30

Registrant information
Name
Narges Aliniya
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-12-22, 1397/10/01
Expected recruitment end date
2019-02-20, 1397/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of a training program on biochemical markers of non-alcoholic fatty liver

Public title
The effect of a training program of non-alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Women 40-60 years old Having a non-alcoholic fatty liver with varying degrees Not having any illness other than fatty liver Being a menopause

Exclusion criteria:

Having heart-respiratory disease, kidney, hypertension Acute diseases such as viral hepatitis and other non-alcoholic liver diseases other than non-alcoholic fatty liver (such as viral hepatitis B, C, autoimmune hepatitis, celiac disease, Wilson, a 1-antithyrium deficiency and hemochromatosis) Alcohol and tobacco use Having regular exercise in the last 6 months, Coagulation disorders, Impairment of the immune system, Pulmonary problems, hypothyroidism Damage to the limb that prevents exercise. Having any surgery, Slight and waning weight loss Chronic or acute liver disorders, cancer, liver transplantation, Pregnancy, breastfeeding, Use of any supplement and medicinal herbs

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method was based on the homogeneity of the ultrasound results or the elevated liver enzyme test, so that each of the four people who had the highest fatty liver or the highest enzyme level were placed in one of the four groups in random order. And so are the next 4 and so on

Blinding (investigator's opinion)

Single blinded

Blinding description

The supplement + exercise group and supplement group receive 2 capsules of 500 mg periphenol capsules per day (manufactured by Pars Health Company and approved by the Institute of Medicinal Plants, Jihad University) and the placebo + + daily exercise will receive 2 placebo capsules (pills containing wheat flour). (Table 3). The control group did not attend any sports program and did not receive any nutritional or supplementary advice. The contents of periphon capsules and nutrient content per 100 grams of purpureum and dietary percentages are listed in Table 4 and 5. To ensure promise, capsules are distributed on a weekly basis, along with the necessary advice (for the amount and timing) of the participants. Both groups will be trained to take capsules every two days after breakfast and dinner. To do this, the capsules were packed in similar packages with the same information and instructions and coded by an individual other than the intervener in the form A, B so that the interceptor did not know the type of capsule received by each Observe the group. Follow-up of supplementation by the subjects is contacted daily by telephone, and the claimed amounts are followed up and information is received. Patients who have not taken their pills are excluded from the study

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Biomedical Research of Islamic Azad University, Rasht Branch

Street address

Golkesh-Golestan Bridge

City

Rasht

Province

Guilan

Postal code

۴۱۴۷۶۵۴۹۱۹

Approval date

2018-12-05, 1397/09/14

Ethics committee reference number

IR. IAU. RASHT.REC. 1397. 034

Health conditions studied

1

Description of health condition studied

non-alcholic fatty liver desease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Cholesterol

Timepoint

Start and end of study

Method of measurement

Radiocommunication

2

Description

LDL

Timepoint

Start and end of study

Method of measurement

Radiocommunication

3

Description

HDL

Timepoint

Start and end of study

Method of measurement

Radiocommunication

4

Description

AST

Timepoint

Start and end of study

Method of measurement

Enzymatic method using kit

5

Description

ALT

Timepoint

Start and end of study

Method of measurement

Enzymatic method using kit

6

Description

ALP

Timepoint

Start and end of study

Method of measurement

Enzymatic method using kit

7

Description

Degree of fatty liver

Timepoint

Start and end of study

Method of measurement

Sonography

Secondary outcomes

1

Description

Body mass index

Timepoint

Start and end of study

Method of measurement

Using scales and centimeters

2

Description

Waist to hip ratio

Timepoint

Start and end of study

Method of measurement

Using centimeters

3

Description

Body fat percentage

Timepoint

Start and end of study

Method of measurement

Caliper

Intervention groups

1

Description

Supplementary group group: 500 Gram pillow after breakfast and dinner for 3 months

Category

Treatment - Drugs

2

Description

Placebo group: Two daily pills containing wheat flour for 3 months

Category

Treatment - Drugs

3

Description

Exercise group: Aerobic and resistance training for 3 months

Category

Treatment - Devices

4

Description

Exercise + exercise group: 3 months of aerobic-resilient activity plus supplements

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ultrasound Center

Full name of responsible person

Narges Aliniya

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Farabi Street- Ultrasound Center

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor For Research Of Azad University
Full name of responsible person
Seyyed Mozaffar Mirberg Working.
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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-Chancellor For Research Of Azad University
Proportion provided by this source
100
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
Persons

Person responsible for general inquiries

Contact
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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