Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Effects of resistance training and curcumin supplementation on the liver biochemical markers levels and structure in old women with non-alcoholic fatty liver disease

Protocol summary

Study aim
Examine the effects of nonlinear resistance training and curcumin supplementation on the liver structure and biochemical markers in obese old women with non-alcoholic fatty liver disease.

Design
Double blinded study

Settings and conduct
Forty-five obese women with non-alcoholic fatty liver disease were randomly assigned into resistance training, curcumin supplement, resistance training with curcumin supplement and placebo groups. The training groups received 12-weeks of nonlinear resistance training while control groups had a normal sedentary lifestyle. Daily, supplement groups received a curcumin capsule while plasebo group was given a placebo capsule. Blood sampling and ultrasonography were taken before and after the protocol.

Participants/Inclusion and exclusion criteria
Inclusion criteria consisted of being obese, elderly (60-71 years old) and female in addition to having fatty liver disease. The exclusion criteria were as follows: addiction to smoking, alcohol abuse, doing regular physical exercises in the last 6 months, having lung disease, kidney disease, cardiovascular disease, liver transplantation, estrogen intake, high blood pressure, chronic disorders, taking special medications such as statins, having a special dietary program, allergy to curcumin, having a cancer record and taking other supplements.

Intervention groups
Resistance training, curcumin, resistance training with curcumin and placebo.

Main outcome variables
Alanine aminotransferase (ALT); Alkaline phosphatase (ALP); Aspartate aminotransferase (AST); Platelet counts; Total bilirubin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190103042219N1**
Registration date: **2019-12-14, 1398/09/23**
Registration timing: **retrospective**

Last update: **2019-12-14, 1398/09/23**
Update count: **0**

Registration date
2019-12-14, 1398/09/23

Registrant information

Name
Mohammad Ali Azarbayjani

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
2016-10-22, 1395/08/01

Expected recruitment end date
2016-11-21, 1395/09/01

Actual recruitment start date
2016-10-31, 1395/08/10

Actual recruitment end date
2016-12-21, 1395/10/01

Trial completion date
2018-04-21, 1397/02/01

Scientific title
Effects of resistance training and curcumin supplementation on the liver biochemical markers levels and structure in old women with non-alcoholic fatty liver disease

Public title
Effects of resistance training and curcumin on fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being obese Elderly (60-71 years old) Female Having fatty liver disease Untrained

Exclusion criteria:
Addiction to smoking Alcohol abuse Doing regular physical exercises in the last 6 months Having lung disease Kidney disease Cardiovascular disease Liver transplantation Estrogen intake High blood pressure Chronic disorders Taking special medications such as statins Having a special dietary program Allergy to curcumin Having a cancer

Age
From **60 years** old to **71 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **45**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Each subject was assigned a code. The codes were given to an uninformed person who was also the master of the plan. The teacher found 45 randomly codes by using the Internet and assigned to each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Subjects were identified using the code. Subjects were categorized by a unknown and groups has code. Only the code was given to the lab and the name of the subject and group was not specified. Only the code was given to the analysis. The supplement and placebo subjects were unaware of their group name.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University, Kazeroun Branch, Iran with ethical code: IR.IAU.KAU.REC.1398.079

Street address
Islamic Azad university

City
Kazeroun

Province
Fars

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9845476003

Approval date
2019-09-26, 1398/07/04

Ethics committee reference number
IR.IAU.KAU.REC.1398.079

Health conditions studied

1

Description of health condition studied
Fatty liver

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Liver enzymes, including alanine transaminase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP)

Timepoint
Blood samples were taken before the intervention and 48 hours after 8 weeks of training.

Method of measurement
ALT, AST, ALP levels were measured by Pars Azmon Kit.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Resistance training: 1-The warm-up consisted of working out with a fixed bike for 8 minutes and 5 minutes of light stretching exercises. 2- The

nonlinear resistance training program used in this study has been proposed by Nikseresht et al. (Nikseresht et al., 2014). Each session took about 60-70 minutes for main training (plus about 20 minutes for warm-up and cool-down), three days a week (nonconsecutive) which lasted 12 weeks.

Category

Treatment - Other

2

Description

Intervention group: Curcumin supplement: Participants in supplement groups were asked to take one curcumin capsule (Curcumin 80 mg as Nanomicelle produced by Minoo Pharmaceutical Co.) per day after breakfast.

Category

Treatment - Drugs

3

Description

Intervention group: Resistance training with curcumin supplement. This group has curcumin supplementation plus non-liner resistance exercise training.

Category

Treatment - Drugs

4

Description

Control group: Plasebo. Has no exercise training and take one placebo capsule per day after breakfast for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan University of Medical Science

Full name of responsible person
Mohammad Ali Azarbayjani PHD

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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Grant name
Vice of Research, Central Branch, Islamic Azad University

Grant code / Reference number

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

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Public

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
Islamic Azad University

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Mohammad Ali Azarbayjani

Position
Prof

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Biochemistry

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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
Yes - There is 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Liver enzyme

When the data will become available and for how long
4 month

To whom data/document is available
Researchers

Under which criteria data/document could be used
For article

From where data/document is obtainable
Researcher

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

Comments