Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of aerobic training and vitamin D supplementation on liver Fat, liver enzymes and lipid profile in elderly women with nonalcoholic fatty liver and vitamin D deficiency

Protocol summary

Study aim

Evaluation of the interactional effects of 8 weeks of vitamin D supplementation and aerobic training on the fatty liver level, serum levels of liver enzymes (ALT and AST), lipid profile, and body composition in elderly women with Nonalcoholic fatty liver and vitamin D deficiency

Design

Clinical trials with a control group, and purposive sampling model

Settings and conduct

This clinical trial study will be conducted on the effects of aerobic training with Vit D supplementation on NAFLD patients in pre-test and post-test form.

Participants/Inclusion and exclusion criteria

Inclusion criteria will be include ultrasound (US) confirmation of being in second or third grade of NAFLD and certified by an internist, 25-OHD serum levels between 10 and 20 ng/ml, not having a specific diet and regular exercise program in the past year. Exclusion criteria include; significant consumption of alcohol more than 20 gr per day, presence of other liver diseases (B and C hepatitis), other disorders such as autoimmune hepatitis and ..., also surgical treatment of obesity or severe weight loss, and the presence of any other chronic disease or skeletal disorders

Intervention groups

Aerobic training (placebo); Vitamin D supplementation (no AT); Aerobic training with vitamin D supplements (AT+Vit D); and Control (placebo+no AT).

Main outcome variables

Vitamin D levels, liver fat levels, serum levels of liver enzymes, lipid profiles, body composition, blood pressure, insulin, glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190423043359N1**
Registration date: **2019-08-15, 1398/05/24**
Registration timing: **retrospective**

Last update: **2019-08-15, 1398/05/24**
Update count: **0**

Registration date

2019-08-15, 1398/05/24

Registrant information

Name
Zahra Hoseini
Name of organization / entity
Razi University, Kermanshah
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-12, 1397/09/21

Expected recruitment end date

2019-01-11, 1397/10/21

Actual recruitment start date

2018-12-12, 1397/09/21

Actual recruitment end date

2019-01-11, 1397/10/21

Trial completion date

2019-03-19, 1397/12/28

Scientific title
Effect of aerobic training and vitamin D supplementation on liver Fat, liver enzymes and lipid profile in elderly women with nonalcoholic fatty liver and vitamin D deficiency

Public title
Effect of aerobic training and vitamin D supplementation on liver Fat, liver enzymes and lipid profile

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Ultrasound (US) confirmation of being in second or third grade of NAFLD and certified by an internist 25-OHD serum levels between 10 and 20 ng/ml Being in second or third grade of NAFLD Not having a specific diet and regular exercise program in the past year
Exclusion criteria:
Significant consumption of alcohol more than 20 gr per day Presence of other liver diseases (B and C hepatitis) Other disorders such as autoimmune hepatitis, joint disease, celiac and Wilson disease, coronary artery disease, kidney failure, hypothyroidism Surgical treatment of obesity or severe weight loss Presence of any other chronic disease or skeletal disorders

Age
From **60 years** old to **65 years** old

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Forty subjects will be randomly divide into four groups includes Aerobic training (AT, n=10); Vitamin D supplementation (Vit D, n=10); Aerobic training with vitamin D supplements (AT+Vit D, n=10); and control (C, n=10) using statistical software. Each participant will have an equal chance of being in each group, and researchers and participants in the study will not be able to predict the type of intervention they receive.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
No. 8, Beheshti Blvd, Kermanshah Province, Kermanshah University of Medical Sciences.
City
Kermanshah
Province
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Postal code
6715847141

Approval date
2019-03-06, 1397/12/15

Ethics committee reference number
IR.KUMS.REC.1397.1059

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease

ICD-10 code
K76.0

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

Primary outcomes

1

Description
liver fat levels

Timepoint
Evaluation of fatty liver grade prior to the intervention and 24-48 h after intervention finished

Method of measurement
Using ultrasound (US)

2

Description
Vitamin D levels

Timepoint
Prior to the beginning and at the end of the study

Method of measurement
By blood sampling

3

Description
Anthropometric indices

Timepoint
Before the study starts and after the study ends

Method of measurement
Using INBODY test

4

Description
Lipid profile
Timepoint
Before the study starts and after it ended.
Method of measurement
Blood sampling

5

Description
serum levels of liver enzymes
Timepoint
Before the study starts and after it ended.
Method of measurement
Blood sampling

6

Description
glucose and insulin levels
Timepoint
Before the study starts and after it ended.
Method of measurement
Blood sampling

7

Description
blood pressure
Timepoint
Before the study starts and after it ended.
Method of measurement
Digital sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
The aerobic training + vitamin D supplementation Intervention will be consists of 20-40 minutes of aerobic exercise at 60% - 75% of HRmax, 3 times a week for eight weeks and vitamin D supplementation will be receiving vitamin D (~50000 IU • week for eight weeks).
Category
Lifestyle

2

Description
Intervention group: Aerobic training consists of 20-40 minutes of aerobic exercise at 60% - 75% of HRmax, 3 times a week for eight weeks.
Category
Lifestyle

3

Description
Intervention group: Vitamin D supplementation includes receiving vitamin D (~50000 IU • week for eight weeks).
Category
Lifestyle

4

Description
Control group: receiving placebo and no aerobic training for eight weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam hosein hospital
Full name of responsible person
Zahra hoseini
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No.9, Taqh-Bostan Ave, University Blvd, Razi University.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razi University
Full name of responsible person
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Email

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Web page address

https://razi.ac.ir/

Grant name

no

Grant code / Reference number

0000000000000000000000000000000000000000

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

Yes

Title of funding source

Razi University

Proportion provided by this source

10

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Razi University

Full name of responsible person

Rastegar Hoseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Master

Other areas of specialty/work

Others

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data will be record in the SPSS software and will be available.
When the data will become available and for how long
Availability will start nine months after publishing all papers
To whom data/document is available
Only available for researchers in academic and scientific institutions
Under which criteria data/document could be used
All data can be used as reference
From where data/document is obtainable
Zahra.hoseinir@gmail.com
What processes are involved for a request to access data/document
If the explanation for data request would be convincing it will be given in 3 days.
Comments
not having any