Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Alterations of liver enzymes and lipid profile in response to exhausting eccentric exercise after short-term vitamin D supplementation in the overweight female with non-alcoholic fatty liver

Protocol summary

Study aim

Evaluation of alterations of liver enzymes and lipid profile in response to exhausting eccentric exercise after short-term vitamin D supplementation in the overweight female with non-alcoholic fatty liver

Design

The present study is a randomized single-blind clinical trial with control group on patients with with non-alcoholic fatty liver.

Settings and conduct

30 samples were divided into experimental group (vitamin D recipient) and placebo (oral paraffin recipient) using a simple random sampling method . every groups received diet using adjusted ideal body weight. Macronutrient distribution in diet will be given in the form of 65-45% CHO, 10-15% and 30-35% fat. In this study, there are 2 visits for the patient at the beginning, and the end of the study. This study was conducted in the form of single-blind that patients and physicians be unaware of the type of intervention that they were taking.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with non-alcoholic fatty liver/ 20 to 30 years/overweight; no use of any drug and / or surgical treatment; Not having any systemic disease and other endocrine disorders; Lack of Pregnancy and Breastfeeding Exclusion criteria: Start taking or any dose changes in medications and participate in regular physical activity

Intervention groups

In this study, one group receiving vitamin D as intervention group and one group receiving oral paraffin as a control group.

Main outcome variables

Anthropometric indices, liver enzymes, lipid profile, insulin resistance and quality of life in patients with nonalcoholic fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201130049538N1**
Registration date: **2021-07-05, 1400/04/14**
Registration timing: **retrospective**

Last update: **2021-07-05, 1400/04/14**
Update count: **0**

Registration date

2021-07-05, 1400/04/14

Registrant information

Name

Zahra Rahim pour

Name of organization / entity

Razi University of Kermanshah

Country

Iran (Islamic Republic of)

Phone

+98 83 3431 1518

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-10, 1400/02/20

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Alterations of liver enzymes and lipid profile in response to exhausting eccentric exercise after short-term vitamin D supplementation in the overweight female with non-alcoholic fatty liver

Public title
Short-term effect of vitamin D on liver enzymes and lipid profile in response to exhausting eccentric exercise

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
Overweight women with non-alcoholic fatty liver Age 20 to 30 years Body mass index above 25 to 29.99 Detection of non-alcoholic fatty liver by ultrasound Vitamin D deficiency (25 levels of hydroxyvitamin D below 30 nanomoles / liter)

Exclusion criteria:
Muscle injury Uncontrolled intake of vitamin D supplements Doing regular exercise smoking

Age
From **20 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple random sampling method will be used; And because the study population is small, the lottery method is used, That is, the names of the people are written on a piece of paper and placed inside the box, then the papers are taken out one by one until the desired sample size is complete.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, participants and health care personnel will be unaware of the type of intervention each patient receives. It should be noted that only the lead researcher will be aware of the intervention received for each patient.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah Razi University

Street address
No.9, Taqh-Bostan Ave, University Blvd, Razi University.

City
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Kermanshah

Postal code
6714967346

Approval date
2021-02-24, 1399/12/06

Ethics committee reference number
IR.RAZI.REC.1399.079

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
Lipid profile

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

Method of measurement
By blood sampling

2

Description
serum levels of liver enzymes

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

Method of measurement
By blood sampling

3

Description
glucose and insulin levels

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

Method of measurement
By blood sampling

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Fourteen subjects, Vitamin D supplementation (including receiving vitamin D from Zahravi Pharmaceutical Company, at the rate of 2000 units per day for six weeks), Exhaustive test and negative slope on the treadmill for two sessions (one session before supplementation and one session after supplementation), Control the intensity of exercise using a polar heart rate monitor and the Borg index, Blood sampling in four rounds. The first and second stages of sampling before and after the first training protocol and the third and fourth stages of sampling after the completion of the second training protocol.
Category
Lifestyle

2

Description
Control group: Fourteen subjects, Receive a placebo containing paraffin made by Zahravi Pharmaceutical Company of Iran (daily for six weeks) which is similar to vitamin D supplement in terms of shape, color, smell and taste. Exhaustive test and negative slope on the treadmill for two sessions (one session before supplementation and one session after supplementation), Control the intensity of exercise using a polar heart rate monitor and the Borg index, Blood sampling in four rounds. The first and second stages of sampling before and after the first training protocol and the third and fourth stages of sampling after the completion of the second training protocol.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam hosein hospital
Full name of responsible person
Zahra Rahimpour
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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 Univeristy
Full name of responsible person
Rastegar Hoseini
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Nutrition
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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.rahimpour73@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