

# 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

zahra.rahimpour.73@gmail.com

##### 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 science

### 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

Kermanshah

##### Province

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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**Email**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Razi University

**Full name of responsible person**

Rastegar Hoseini

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**Email**

R.hoseini@Razi.ac.ir

**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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Razi University

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Razi University

**Full name of responsible person**

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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