

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Interactional and separate effects of aerobic training and vitamin D supplementation on genes expression of inflammation and oxidative stress in men with type 2 diabetes

#### Protocol summary

##### Study aim

The aim of this study was to investigate the interactional and separate effects of aerobic training and vitamin D supplementation on genes expression of inflammation and oxidative stress in men with type 2 diabetes

##### Design

For this purpose, 40 men with type 2 diabetes will be randomly divided into 4 groups: aerobic training + vitamin supplementation, aerobic training, vitamin D supplementation and control, as well as vitamin D intake (about 50,000 IU= 1/25 mg per week for eight weeks); Or it will be a placebo. The aerobic training protocol includes 20 to 40 minutes of aerobic exercise with an intensity of 60 to 75% of the maximum heart rate, 3 times a week for eight weeks.

##### Settings and conduct

This study was a clinical trial on the aerobic training and vitamin D supplementation on genes expression of inflammation and oxidative stress in men with type 2 diabetes under the supervision of HALABJA University. Pre-test and post-test will be performed.

##### Participants/Inclusion and exclusion criteria

Non-insulin dependent type 2 diabetes; HbA1C above 6; no antioxidants; multivitamin and polyphenol supplements in the last three months; having index body mass (25 to 29.99 kg / m<sup>2</sup>)

##### 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; genes expression of inflammation and Oxidative stress

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210811052151N1**  
Registration date: **2021-09-01, 1400/06/10**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-09-01, 1400/06/10**

Update count: **0**

##### Registration date

2021-09-01, 1400/06/10

##### Registrant information

###### Name

Rastegar Hoseini

###### Name of organization / entity

Razi University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3423 3267

###### Email address

r.hoseini@razi.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-01, 1400/06/10

##### Expected recruitment end date

2021-10-02, 1400/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Interactive and separate effects of aerobic training and vitamin D supplementation on genes expression of inflammation and oxidative stress in men with type 2 diabetes

### Public title

The effect of aerobic exercise and vitamin D supplementation on inflammation in men with type 2 diabetes

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Suffering non-insulin dependent type 2 diabetes Fasting blood sugar above 126 Do not take antioxidants and multivitamin and polyphenol supplements in the last three months Body mass index (25 to 29.99 kg/per square meter) HbA1C above 6

#### Exclusion criteria:

Changes in the amount and type of medication taken, physical activity and diet during the study period Fasting blood sugar greater than 200 mg / dL LDL greater than 160 mg / dL Having Heart disease, renal failure, liver

### Age

From **30 years** old to **50 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Razi University of Kermanshah

##### Street address

No. 8, University Blvd, Kermanshah Province, Kermanshah University of Medical Sciences

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714414971

##### Approval date

2021-06-23, 1400/04/02

##### Ethics committee reference number

IR.RAZI.REC.1400.044

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Type 2 diabetes mellitus

## 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

Glycemic indexes

#### Timepoint

Prior to the beginning and at the end of the study

#### Method of measurement

By Blood sampling

### 3

#### Description

Anthropometric indicators

#### Timepoint

Prior to the beginning and at the end of the study

#### Method of measurement

The quantitative measurement tools

### 4

#### Description

Genes expression of inflammation

#### Timepoint

Prior to the beginning and at the end of the study

#### Method of measurement

By Blood sampling

### 5

#### Description

Oxidative stress

#### 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 group1: Aerobic training + vitamin D supplementation group: 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 online and vitamin D supplementation will be receiving vitamin D (~50000 IU • week for eight weeks) receiving vitamin D (about 50,000 IU per week for 8-weeks).

#### **Category**

Lifestyle

##### 2

#### **Description**

Intervention group 2: Aerobic training group: Aerobic training consists of 20 to 40 minutes of aerobic exercise with an intensity of 60 to 75 % of maximum heart rate, 3 times a week for eight weeks online.

#### **Category**

Lifestyle

##### 3

#### **Description**

Intervention group 3: Vitamin D supplementation group: Vitamin D supplementation includes receiving vitamin D (~50000 IU • week for eight weeks).

#### **Category**

Lifestyle

##### 4

#### **Description**

Control group: Receiving placebo (containing paraffin made by Zahravi Pharmaceutical Company of Iran which is similar to vitamin D supplement in terms of shape, color, smell and taste) and no aerobic training for eight weeks.

#### **Category**

Lifestyle

#### **Recruitment centers**

##### 1

#### **Recruitment center**

##### **Name of recruitment center**

Diabetes Center

##### **Full name of responsible person**

Rastegar Hoseini

#### **Street address**

Faculty of Physical Education and Sports Sciences, Kermanshah, No. 9, Razi University Blvd.

#### **City**

Kermanshah

#### **Province**

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#### **Postal code**

6714967346

#### **Phone**

+98 83 3432 2768

#### **Email**

R.hoseini@razi.ac.ir

#### **Sponsors / Funding sources**

##### 1

#### **Sponsor**

##### **Name of organization / entity**

Razi University

##### **Full name of responsible person**

Dr. Farzad Veys

##### **Street address**

No. 9, Razi University, Daneshgah Blvd., Bostan St., Kermanshah

##### **City**

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Kermanshah

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6714967346

##### **Phone**

+98 83 3423 3278

##### **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**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

Sponsor: country of origin

#### **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**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise Physiology

**Street address**

No. 9, Razi University, Faculty of Physical Education and Sports Sciences, Daneshgah Blvd., University Boulevard, Kermanshah, Kermanshah

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Rastegar.hoseini@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Razi University

**Full name of responsible person**

Rastegar Hoseini

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Razi University

**Full name of responsible person**

Rastegar Hoseini

**Position**

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**Email**

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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**

R.hoseini@razi.ac.ir

**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**