

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 / m²)

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

Kermanshah

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

Kermanshah

Province

Kermanshah

Postal code

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

City

Kermanshah

Province

Kermanshah

Postal code

6714967346

Phone

+98 83 3432 2768

Email

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

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

City

Kermanshah

Province

Kermanshah

Postal code

6714967346

Phone

+98 83 3432 2768

Email

R.hoseini@razi.ac.ir

Person responsible for updating data**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

City

Kermanshah

Province

Kermanshah

Postal code

6714967346

Phone

+98 83 3432 2768

Email

R.hoseini@razi.ac.ir

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