Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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

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