Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Eight Weeks Aerobic Training with Vitamin D Supplementation on Cardiac Biomarkers, VEGF-B Protein Levels, IGF-1 and Mir-1 Gene Expression in Cardiomyocytes of Type 2 Diabetic Rats.

Protocol summary

Study aim

This study aims to determine the effect of eight weeks of aerobic training with vitamin D supplementation on cardiac biomarkers, VEGF-B protein levels, and IGF-1 and Mir-1 gene expression in cardiomyocytes of type 2 diabetic rats.

Design

A randomized clinical trial with pre and post-test design, including six experimental, two control, and one sham group on 90 types 2 diabetic rats. The random number table method was used for randomization.

Settings and conduct

To determine the effect of eight weeks of aerobic training with vitamin D supplementation on cardiomyocytes of type 2 diabetic rats, this study will be done in the biology laboratory of Basic Sciences College of Razi University, under the supervision of Physical Education and Sports Science College of Razi University. In summary, after a one-week-familiarization, the main protocol (including vitamin D injection one time per week and aerobic training five times per week) will be done for eight weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 2 to 3 months old; to have a minimum of 300 grams of weight; to have type 2 diabetes mellitus in diabetic groups; not to have type 2 diabetes mellitus in non-diabetic obese groups; male sex. Exclusion criteria: movement disabilities.

Intervention groups

1- Aerobic training group (type 2 diabetic models); 2- Aerobic training with vitamin D supplementation group (type 2 diabetic models); 3- Vitamin D supplementation group (type 2 diabetic models); 4- Aerobic training group (non-diabetic obese models); 5- Aerobic training with vitamin D supplementation group (non-diabetic obese models); 6- Vitamin D supplementation group (non-diabetic obese models); 7- Control group (type 2 diabetic models); 8-Control group (non-diabetic obese models); 9-Sham group.

Main outcome variables

Cardiac biomarkers; VEGF-B protein; IGF-1 and Mir-1 genes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220512054832N1**
Registration date: **2022-06-09, 1401/03/19**
Registration timing: **prospective**

Last update: **2022-06-09, 1401/03/19**
Update count: **0**

Registration date

2022-06-09, 1401/03/19

Registrant information

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Fatemeh Mazaheri
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Razi University of Kermanshah
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Eight Weeks Aerobic Training with Vitamin D Supplementation on Cardiac Biomarkers, VEGF-B Protein Levels, IGF-1 and Mir-1 Gene Expression in Cardiomyocytes of Type 2 Diabetic Rats.

Public title

The Effect of Aerobic Training with Vitamin D Supplementation on Cardiomyocytes Gene Expression of Type 2 Diabetic Rats.

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 2 to 3 months old To have a minimum of 300 gram of weight To have type 2 diabetes in diabetic groups No to have type 2 diabetes in non-diabetic obese groups Male sex

Exclusion criteria:

Movement disabilities

Age

From **2 months** old to **3 months** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number tables were used for randomization. For this purpose, every 90 rats got a specific number from 1 to 90. Then, using the RAND function of Excel software (Microsoft Corporation, 2019 version), the random number table was produced. Randomly, with closed eyes, one of the excel worksheet cells was clicked on; that number was considered the origin. Because 90 (subjects quantity) is a two-digit number, the first two digits of the numbers listed on the table were read. In case of being in the range of 1 to 90, that number was allocated to the related group. About the group order that is presented in the intervention groups part, the first 10 numbers were allocated to the first group (Aerobic training, type 2 diabetic models). The members of other groups were chosen in this way, too; that is, the second 10 numbers were allocated to the second group, the third 10 numbers to the third group, and so on.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

In this study, there are three training, supplementation, and training with supplementation groups in diabetic models; three training, supplementation, and training with supplementation groups in non-diabetic obese models; a diabetic group that receives a placebo; a non-diabetic obese group that receives a placebo; and a sham group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Razi University of Kermanshah

Street address

Razi University, Daneshgah Blvd, Taq-e Bostan Ave

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Postal code

6714414971

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.RAZI.REC.1401.011

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Cardiac biomarkers

Timepoint

Before & after the intervention.

Method of measurement

Elisa kit (Elabscience Company) with a sensitivity of 18,75 Pg/mL.

2

Description

Vascular Endothelial Growth Factor B

Timepoint

Before & after the intervention.

Method of measurement

Elisa kit (BT-LAB Company) with a sensitivity of 5.01 ng/L.

3

Description

microRNA 1

Timepoint

Before & after intervention.

Method of measurement

Polymerase chain reaction (PCR) method using The Corbett Research Rotor-Gene 6000 (QIAGEN company) and The miScript SYBR Green PCR Kit (QIAGEN company) with a sensitivity of 1.55 ng/ml.

4

Description

Insulin-like growth factor 1

Timepoint

Before & after the intervention.

Method of measurement

Polymerase chain reaction (PCR) method using The Corbett Research Rotor-Gene 6000 (QIAGEN company) and The Transcriptor First Strand cDNA Synthesis Kit (Roche company) with a sensitivity of 1.55 ng/ml.

Secondary outcomes

1

Description

Lipid profile

Timepoint

Before & after the intervention.

Method of measurement

Photometry method using Pars Azmoun company kits. The sensitivity of serum level assay kit for LDL Cholesterol, HDL Cholesterol, Triglyceride, and Glucose equals 12.098 mg/dL, 22.714 mg/dL, 35.087 mg/dL, and 25.497 mg/dL, respectively.

Intervention groups

1

Description

Intervention group one (Aerobic training, type 2 diabetic models): Aerobic training for eight weeks (50-60% of maximum oxygen consumption for 25-60 minutes, five times per week).

Category

Treatment - Other

2

Description

Intervention group two (Aerobic training with vitamin D supplementation, type 2 diabetic models): Aerobic training for eight weeks (50-60% of maximum oxygen consumption for 25-60 minutes, five times per week); Receiving vitamin D for eight weeks (5000 IU per week).

Category

Treatment - Other

3

Description

Intervention group three (Vitamin D supplementation, type 2 diabetic models): Receiving vitamin D for eight weeks (5000 IU per week).

Category

Treatment - Other

4

Description

Intervention group four (Aerobic training, non-diabetic obese models): Aerobic training for eight weeks (50-60% of maximum oxygen consumption for 25-60 minutes, five times per week).

Category

Treatment - Other

5

Description

Intervention group five (Aerobic training with vitamin D supplementation, non-diabetic obese models): Aerobic training for eight weeks (50-60% of maximum oxygen consumption for 25-60 minutes, five times per week); Receiving vitamin D for eight weeks (5000 IU per week).

Category

Treatment - Other

6

Description

Intervention group six (Vitamin D supplementation, non-diabetic obese models): Receiving vitamin D for eight weeks (5000 IU per week).

Category

Treatment - Other

7

Description

Control group one (type 2 diabetic models): Receiving placebo without aerobic training for eight weeks.

Category

Placebo

8

Description

Control group two (non-diabetic obese models): Receiving placebo without aerobic training for eight weeks.

Category

Placebo

9

Description
Sham group: The subjects of this group are just placed on the treadmill and do not do aerobic training.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
College of Pharmacy of Kermanshah University of Medical Sciences
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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?
Yes
Title of funding source
Razi University of Kermanshah
Proportion provided by this source
100
Public or private sector
Public
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
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Other areas of specialty/work
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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
No - There is not 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 the data are presentable.
When the data will become available and for how long
The data can be accessed 9 months after their publication.
To whom data/document is available
Only researchers of academic and scientific institutes can access the data.
Under which criteria data/document could be used
Considering the author's rights, all the data can be utilized.
From where data/document is obtainable
1- Dr. Rastegar Hosseini (rastegar.hoseini@gmail.com).
2- Fatemeh Mazaheri (fatemehmazaheri377@gmail.com).
What processes are involved for a request to access data/document
At first, one will send their request via email. After revision and in case of expediency, in 3-10 working days, the related information will be presented to them.
Comments