Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Eight Weeks Aerobic Training with Vitamin D Supplementation on AMPK, PGC-1a, PTP1B, and UCP-1 Gene Expression in The Visceral Adipose Tissue of Obese Rats with Type 2 Diabetes

Protocol summary

Study aim

The purpose of this study is to answer the question "Does eight weeks of aerobic exercise with vitamin D supplementation have any effect on expression of AMPK, PGC-1a, PTP1B and UCP-1 genes in visceral adipose tissue of obese rats with type 2 diabetes?".

Design

A randomized clinical trial with pre and post test design, along with six experimental, two control and a sham group on 90 type 2 diabetic rats. Lottery method was used for randomization.

Settings and conduct

This study with pre and post test design will be done, under supervision of physical education and basic sciences colleges, in order to determine the effect of aerobic training with vitamin D supplementation on AMPK, PGC-1a, PTP1B and UCP-1 gene expression in visceral adipose tissue of obese rats with type 2 diabetes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 2-3 months; having at least 300 gram weight; being type 2 diabetic patient; male gender. Exclusion criteria: movement disabilities.

Intervention groups

Control group (type 2 diabetes), training group (type 2 diabetes), vitamin D supplementation group (type 2 diabetes), training + vitamin D supplementation group (type 2 diabetes), Control group (obese without type 2 diabetes), training group (obese without type 2 diabetes), training + vitamin D supplementation group (obese without type 2 diabetes), vitamin D supplementation group (obese without type 2 diabetes), sham group.

Main outcome variables

AMPK gene expression; Expression of PGC-1a gene; Expression of PTP1B gene; UCP-1 gene expression; Irisin gene expression; Insulin resistance index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220510054809N1**
Registration date: **2022-06-27, 1401/04/06**
Registration timing: **prospective**

Last update: **2022-06-27, 1401/04/06**
Update count: **0**

Registration date

2022-06-27, 1401/04/06

Registrant information

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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
Effect of Eight Weeks Aerobic Training with Vitamin D Supplementation on AMPK, PGC-1a, PTP1B, and UCP-1 Gene Expression in The Visceral Adipose Tissue of Obese Rats with Type 2 Diabetes

Public title
Effect of Aerobic Training with Vitamin D Supplementation on Gene Expression of Visceral Adipose Tissue of Obese Rats with Type 2 Diabetes

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
Age between8 to 9 months old Male sex To have type 2 diabetes in diabetic groups To have a minimum of 300 gram of weight No to have type 2 diabetes in non-diabetic obese groups

Exclusion criteria:
Movement disabilities

Age
From **8 months** old to **9 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
At first, any qualified rat got a specific code. then, the codes was written on a similar piece of paper and placed in the first vase. Also, the name of groups was written on a similar piece of paper and placed in the second vase. In the following, after blending the papers in any vase, a code were drawn from first vase and assigned to the group that its name were drawn from the second vase, respectively. In case of completing the desired members of any group before ending the lottery, the name of that group was excluded from its vase.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

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
Ethics committee in research of Razi University of Kermanshah

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Approval date
2022-04-19, 1401/01/30

Ethics committee reference number
IR.RAZI.REC.1401.013

Health conditions studied

1

Description of health condition studied
type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes

Primary outcomes

1

Description
AMPK Gene Expression

Timepoint
Before intervention; after intervention.

Method of measurement
Western-Blot method using Kiagen Kit With 0/021 Pg/mL sensitivity.

2

Description
Expression Of PGC-1a Gene

Timepoint
Before intervention; after intervention.

Method of measurement
Real time-PCR Method using Mirnasy mini kit50 Kit With 0/06 ng/mL sensitivity.

3

Description

Expression Of PTP1B Gene

Timepoint

Before intervention; after intervention.

Method of measurement

Real time-PCR Method using RNeasy Commercial Kit With 0/06 ng/mL sensitivity.

4

Description

Expression Of UCP-1 Gene

Timepoint

Before intervention; after intervention.

Method of measurement

Eliza Double Sandwich Method using Cat no: ZB-11252-R9648 Kit With 0/06 ng/mL sensitivity.

5

Description

Insulin Resistance Index

Timepoint

Before intervention; after intervention.

Method of measurement

Serum Insulin by Elisa Method using Micro-calorie Metric Kit With 5/5 mg/dl Sensitivity. Insulin Resistance Index will be Determined Using Glucose And Insulin Concentrations And HOMA-IR formula.HOMA-IR= (Glucose Concentration × Insulin Concentration)÷22/5

Secondary outcomes

1

Description

Irisin Expression Gene

Timepoint

Before intervention; after intervention.

Method of measurement

Eliza Method using EASTBIOPHARM Kit With 0/023 mg/mL sensitivity.

Intervention groups

1

Description

Intervention group 1; Aerobic training (type 2 diabetes): Aerobic exercise between 25-60 minute with 50-60% of maximum oxygen consumption, 5 times per week for 8 weeks

Category

Treatment - Other

2

Description

Intervention group 2; Aerobic training + Vitamin D supplementation (type 2 diabetes): Aerobic exercise between 25-60 minute with 50-60% of maximum oxygen consumption, 5 times per week for 8 weeks; 5000 IU

Category

Treatment - Other

3

Description

Intervention group 3; Vitamin D supplementation (type 2 diabetes): 5000 IU vitamin D supplementation per week for 8 weeks.

Category

Treatment - Other

4

Description

Intervention group 4; Aerobic training (obese without diabetes): Aerobic exercise between 25-60 minute with 50-60% of maximum oxygen consumption, 5 times per week for 8 weeks.

Category

Treatment - Other

5

Description

Intervention group 5; Aerobic training + Vitamin D supplementation (obese without diabetes): Aerobic exercise between 25-60 minute with 50-60% of maximum oxygen consumption, 5 times per week for 8 weeks; 5000 IU

Category

Treatment - Other

6

Description

Intervention group 6; Vitamin D supplementation (obese without diabetes): 5000 IU vitamin D supplementation per week for 8 weeks

Category

Treatment - Other

7

Description

Control group 1; Control (type 2 diabetes): 8 weeks of receiving placebo, without aerobic exercise

Category

Placebo

8

Description

Control group 2; Control (obese without diabetes): 8 weeks of receiving placebo, without aerobic exercise

Category

Placebo

9

Description

Sham group: Being on treadmill without doing exercise.

Category

Other

Recruitment centers

1

Recruitment center

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Razi University
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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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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

All the data are usable with consideration of the authors rights.

From where data/document is obtainable

1- Dr. Rastegar Hosseini (rastegar.hoseini@gmail.com).
2- kimya khaledi (kimyakhaledi19@gmail.com).

What processes are involved for a request to access data/document

For this purpose one can send their request via e-mail to the aforementioned persons; after reviewing the request, in case of discretion, the related data will be presented to them. This process can take long between 3 to 10 days.

Comments