

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of aerobic training with vitamin D supplementation on insulin, Glycosylated hemoglobin, nuclear factor of kappa in type 2 diabetic women

Protocol summary

Study aim

The purpose of this study was to evaluate the simultaneous effects of aerobic training and vitamin D supplementation on blood glucose, insulin, glycosylated hemoglobin, body mass index, waist to hip ratio, and body fat percent in type 2 diabetic patients.

Design

Subjects will be divided into 4 groups of 15 including: Experimental group 1 (perform 12 weeks of aerobic training with vitamin D supplementation), Experimental group 2 (perform 12 weeks of aerobic training with placebo), Experimental group 3 (take vitamin D supplement without any exercise training), and the control group (without any exercise training and without vitamin D supplementation). Two intervention groups that taking vitamin D, they have receive 2 servings of vitamin D (each serving 5000 IU). Experimental groups (1 and 2) will perform progressive aerobic training for 12 weeks, 3 sessions per week, and approximately 70 minutes per session. Before and after 12-week intervention, the measurements of the research variables will be done.

Settings and conduct

Training place (for 12-week) is in the exercise physiology lab of University of Kurdistan.

Participants/Inclusion and exclusion criteria

Participants are women with type 2 diabetes who have no history of vitamin D consumption, as well as have no history of regular training in the past 6 months. These people should have no chronic disease other than diabetes. Indeed, their medicine to control diabetes is metformin tablets.

Intervention groups

Aerobic training group Vitamin D supplementation group

Main outcome variables

Glucose; Insulin; Glycosylated hemoglobin; Nuclear factor of kappa; Waist to hip ratio; Body mass index;

Body fat percent

General information

Reason for update

Acronym

و ديلت D تمرين، ویتامين

IRCT registration information

IRCT registration number: **IRCT20140512017675N2**

Registration date: **2019-08-20, 1398/05/29**

Registration timing: **prospective**

Last update: **2019-08-20, 1398/05/29**

Update count: **0**

Registration date

2019-08-20, 1398/05/29

Registrant information

Name

Dariush Sheikholeslami-Vatani

Name of organization / entity

University of Kurdistan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-24, 1398/06/02

Expected recruitment end date

2019-11-23, 1398/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic training with vitamin D supplementation on insulin, Glycosylated hemoglobin, nuclear factor of kappa in type 2 diabetic women

Public title

The effect of aerobic training and vitamin D supplementation on diabetes indices

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a female sex
Having type 2 diabetes
No history of vitamin D supplementation in the past 6 months
No record of regular exercise training in the past 6 months
No having other chronic diseases other than diabetes
Use of metformin to control of diabetes

Exclusion criteria:

Insulin injection as a drug for the control of diabetes type 2
Being over 60 years old

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

From the list of women with type 2 diabetes at the diabetes association of Sanandaj city, and among those who meet to internal criteria, 60 people were selected in a simple random sampling, then randomly assigned to one of 4 groups. Randomization will be as a lottery method.

Blinding (investigator's opinion)

Single blinded

Blinding description

Subjects and physicians were unaware of how individuals were divided into different groups (taking vitamin D supplement or placebo).

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University research ethics committee of University of Kurdistan

Street address

University of Kurdistan, Pasdaran Blvd, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

66196-14741

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.UOK.REC.1398.026

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**

Blood sugar and insulin levels in type 2 diabetic patients

Timepoint

Before the intervention, and after 12-week of vitamin D supplementation as well as aerobic training

Method of measurement

By human serum kits, and caliper

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Doing 12-week of aerobic training along with Vitamin D3 supplementation. Subjects in this group perform 12 weeks of aerobic training, 3 sessions per week, and each session about 70 minutes. Indeed, they receive Vitamin D3 supplement as 3 doses of 5000 IU per week, after breakfast (at non-training days) and with enough water.

Category

Other

2

Description

Intervention group 2: Doing 12-week of aerobic training along with placebo intake. Subjects in this group perform 12 weeks of aerobic training, 3 sessions per week, and each session about 70 minutes. Moreover, they receive 3 times a week maltodextrin capsules (containing 2 grams) as placebo and in similar manner with the first intervention group.

Category

Other

3

Description

Intervention group 3: Vitamin D3 supplementation without exercise training. They receive Vitamin D3 supplement in interval days as 3 doses of 5000 IU per week, after breakfast and with enough water.

Category

Other

4

Description

Control group: Subjects in this group will have no any regular exercise training or Vitamin D3 intake during the 12-week course.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Kurdistan

Full name of responsible person

Dariush Sheikholeslami-Vatani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Kurdistan

Full name of responsible person

kayomars Karami

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

University of Kurdistan

Proportion provided by this source

1

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

Name of organization / entity

University of Kurdistan

Full name of responsible person

Dariush Sheikholeslami-Vatani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data such as information about the main outcome can be shared.

When the data will become available and for how long

Start of access period one month after publishing results

To whom data/document is available

The data will be available to researchers.

Under which criteria data/document could be used

In order to spread scientific information

From where data/document is obtainable

Electronic Email

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

One week after the receiving the request

Comments