

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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 دېلېت D تمرین، ویتامین

##### 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)

##### Phone

+98 912 225 0724

##### Email address

d.vatani@uok.ac.ir

##### 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

##### Street address

Pasdaran

##### City

Sanandaj

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d.vatani@uok.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Kurdistan

##### Full name of responsible person

kayomars Karami

#### Street address

University of Kurdistan, Pasdaran Blvd, Sanandaj

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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 scientific inquiries

#### Contact

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## Person responsible for updating data

### 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

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