Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 tabletes.

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

تمرین، ویتامین D و دیابت

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
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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 phydifsicians 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
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Full name of responsible person
kayomars Karami

Street address
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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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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