

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Anti-Inflammatory Effects of Vitamin D and Resistance Training in Men with Type 2 Diabetes mellitus and Vitamin D Deficiency

Protocol summary

Study aim

The study aimed to investigate the anti-inflammatory effects of vitamin D and resistance training in men with type 2 diabetes mellitus and vitamin D deficiency.

Design

Forty eight men were randomly divided into four groups including; vitamin D supplements and resistance training group, resistance training group, vitamin D supplementation group, or control group. The trial had a control group, a community-based, factorial double-blinded groups, and simple randomization using random numbers table.

Settings and conduct

This research was conducted in Ardabil city and among type 2 diabetic patients referred to the Diabetes Association of the city. Before and after 12 weeks, blood samples were taken to examine the inflammatory factors of the subjects. Bleeding was done until the end of the intervention for researchers, biochemical laboratory technicians, statisticians, subjects and all testers except one person.

Participants/Inclusion and exclusion criteria

The participants were forty-eight inactive people aged 40-65 who had symptoms of diabetes. Inclusion Criteria: The fasting blood glucose level was higher than 126 mg/dL, HbA1c was less than 9%, and the symptoms of vitamin D deficiency with 25 hydroxyvitamin D were less than 20 ng/ml. Exclusion criteria: People with kidney, cardiovascular, liver and other chronic diseases, as well as patients with a history of regular exercise with a history of supplementation with vitamin D and calcium

Intervention groups

Intervention group 1: Vitamin D and resistance training, intervention group 2: resistance training, intervention group 3: vitamin D supplementation group and intervention group 4: control group

Main outcome variables

Main outcome variables In this study, systemic inflammatory indexes included some interleukins and C-

reactive protein. The effect of 12 weeks of exercise training and vitamin D supplements on them was investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042621N1**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **retrospective**

Last update: **2019-02-27, 1397/12/08**

Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

khalid mohamadzadeh salamat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3328 8661

Email address

kh.mohamadzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-10, 1396/12/19

Expected recruitment end date

2018-06-12, 1397/03/22

Actual recruitment start date

2018-03-10, 1396/12/19

Actual recruitment end date

2018-06-12, 1397/03/22
Trial completion date
 2018-08-23, 1397/06/01

Scientific title
 Anti-Inflammatory Effects of Vitamin D and Resistance Training in Men with Type 2 Diabetes mellitus and Vitamin D Deficiency

Public title
 Effect of exercise training and vitamin D on diabetic patients

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Having type 2 diabetes for at least 2 years Fasting blood glucose more than 126 mg / dL HbA1c less than 9% Vitamin D3 level less than 20 ng / ml
Exclusion criteria:
 History of using medications such as insulin, calcium and vitamin D History of kidney, cardiovascular, liver and other diseases Age under 35 and over 60 Having a regular exercise activity one year before the study

Age
 From **35 years** old to **60 years** old

Gender
 Male

Phase
 N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **55**
 Actual sample size reached: **48**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Depending on the number of subjects and groups, it was decided to divide the groups by simple random method and in an individually style. In that, random numbers table were used to divide the equal groups. Random sequences were also used to allocation concealment groups from non-transparent, sealed envelopes. The randomization process was carried out by researchers and two assistants, but the researchers did not know the type of each group. Specifically, vitamin and placebo groups were blinded for researchers.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 lab technicians and expert statisticians did not know the type of intervention of any of the groups. Subjects and researchers also blinded to vitamin and placebo groups. Capsules containing vitamins and placebo were similar and only one of the practitioner's help was able to relate to the content of vitamin and placebo, and supplement giving was done by this person. He had a list of people in

the groups that provided them with the capsules. This blindness continued until the end of the intervention and analysis of the data.

Placebo
 Used

Assignment
 Factorial

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Azad University of Medical Sciences
Street address
 Saheli and Azadegan interaction-Imam Khomeini Educational Center
City
 Ardabil
Province
 Ardabil
Postal code
 5615731567

Approval date
 2018-01-28, 1396/11/08

Ethics committee reference number
 IR.AIAU.REC.1396.271

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
 Tumor Necrosis Factor-alpha (TNF- α)

Timepoint
 Before the intervention and 12 week after

Method of measurement
 Serum levels were measured by the ELISA method and by biochemical kits, Diaclone , France

2

Description
 Interleukin-6 (IL-6)

Timepoint

Before the intervention and 12 week after

Method of measurement

Serum levels were measured by the ELISA method and by biochemical kits, Diaclone , France

3

Description

C-Reactive Protein

Timepoint

Before the intervention and 12 week after

Method of measurement

Serum levels were measured by the ELISA method and by biochemical kits, Roche Diagnostics Company, Swiss

Secondary outcomes

1

Description

loss weight

Timepoint

Before intervention and 12 weeks after that

Method of measurement

With Scale

Intervention groups

1

Description

Intervention group 1: Resistance training

Category

Rehabilitation

2

Description

Intervention group 2: Vitamin D intake

Category

Treatment - Other

3

Description

Intervention group 3: Resistance training + vitamin D

Category

Treatment - Other

4

Description

Control group: Control without intervention + Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil University of Medical Sciences-Ardabil
Diabetes Association

Full name of responsible person

Shiva Asbaghian

Street address

Intersection of Saheli St. and Azadegan Highway,
Imam Khomeini Hospital

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Phone

+98 45 2225 1401

Fax

+98 45 2225 1401

Email

ArdabilDAss@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Sanandaj Branch

Full name of responsible person

Dr Abdollah refaiee

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6616935391

Phone

+98 87 3328 8661

Email

ict@iausdj.ac.ir

Web page address

<http://www.iausdj.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University, Sanandaj Branch

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

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Khalid Mohamadzadeh Salamat

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6616935391

Phone

+98 87 3328 8661

Email

kh.mohamadzadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Khalid Mohamadzadeh Salamat

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Khalid Mohamadzadeh Salamat

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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

Exercise training and supplementation protocols and Initial consequences

When the data will become available and for how long

2019-2020

To whom data/document is available

All

Under which criteria data/document could be used

Use of data and results to improve the status of diabetic patients

From where data/document is obtainable

Islamic Azad University of Sanandaj website and the Center for Clinical Trials Registration (IRCT)

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

Refer to the above sites

Comments