

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of aerobic exercise and 25 hydroxy vitamin D supplementation on ratio of GLP1 and DPP4 and Insulin resistance In men with type 2 diabetes

Protocol summary

Summary

Objectives: The objective of this study was to investigate the effect of 8 weeks of aerobic training With and without 25-Hydroxy Vitamin D Supplementation on level of GLP1 and DPP4 Serum, Fasting Blood Sugar, Serum Insulin and Insulin Resistant index in Patients with Type 2 Diabetic.

Design: This research will be pre test-post test with control group design. **Setting and conduct:** Among men 40 to 60 years with type 2 diabetes admitted Jesus, son of Mary Hospital in Isfahan, a number of 48 persons voluntarily and in access choice were put in four groups of Aerobic exercise group (12patients), aerobic exercise with 25-Hydroxy Vitamin D supplementation group(12patients), 25-Hydroxy Vitamin D supplementation group (12patients) and control group(12patients). **Participants including major eligibility criteria:** All men with type 2 diabetes who referred to diabetes admitted Jesus, son of Mary Hospital that number 48 people, has a presence in study, Including Aged 40 to 60 years! Not doing regular physical activity! Do not use Insulin! Lack of complications of diabetes Including Diabetic foot ulcers! Blood glucose less than 250(mg/dl)! HBA1C Less than 8, choice and put in four groups of Aerobic exercise group (12patients), aerobic exercise with 25-Hydroxy Vitamin D supplementation group(12patients), 25-Hydroxy Vitamin D supplementation group (12patients) and control group(12patients). **Intervention:** Exercise program was include 8 weeks (3sessions in week, each session 60-75 minutes, the intensity of exercise was 60 to 80 percent of maximum heart rate). supplemented groups also received 50000 units of oral vitamin D daily for 8 weeks. **main outcome:** Level of GLP1 and DPP4, Fasting Blood Sugar, Serum Insulin and Insulin Resistant

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010315812N3**

Registration date: **2017-03-08, 1395/12/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-08, 1395/12/18

Registrant information

Name

Naser Rahimi

Name of organization / entity

Hamedan University

Country

Iran (Islamic Republic of)

Phone

+98 813829614

Email address

n.rahimi2009@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Bu Ali Sina University in Hamedan

Expected recruitment start date

2017-01-14, 1395/10/25

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aerobic exercise and 25 hydroxy vitamin D supplementation on ratio of GLP1 and DPP4 and Insulin resistance In men with type 2 diabetes

Public title

Effect of aerobic exercise and 25 hydroxy vitamin D supplementation on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Terms of enter the major conditions: Male: Type 2 diabetes Infection according to diagnosis and medical records for more than a year: Aged 40 to 60 years: Not doing regular physical activity: Do not use Insulin: Lack of complications of diabetes Including Diabetic foot ulcers: Blood glucose less than 250(mg/dl): HBA1C Less than 8. Exclusion major conditions: Absence in the exercise: Lack of supplementation in doses specified: Consumption Insulin.

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

000

Secondary trial Id

0000

Registration date

2017-11-21, 1396/08/30

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Pajuhesh Square, Hamedan

City

Hamedan

Postal code**Approval date**

2017-01-18, 1395/10/29

Ethics committee reference number

IR.UMSHA.REC.1395.467

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Glucagonlike Peptide -1(GLP1)

Timepoint

The first day and 8 weeks after

Method of measurement

Elisa

2**Description**

Dipeptidyl Peptidase-4

Timepoint

The first day and 8 weeks after

Method of measurement

Elisa

3**Description**

Insulin Resistant

Timepoint

The first day and 8 weeks after

Method of measurement

Fasting Blood Sugar*Serum Insulin /405

Secondary outcomes**1****Description**

Serum Insulin

Timepoint

The first day and 8 weeks after

Method of measurement

Blood Sample

2

Description

Fasting Blood Sugar

Timepoint

The first day and 8 weeks after

Method of measurement

Elisa

Intervention groups

1

Description

Control group : This group have not any physical activity or 25-hydroxyvitamin D3 supplements

Category

Treatment - Drugs

2

Description

Aerobic exercise group : Exercise program will be include 8 weeks (3sessions in week, each session 60-75 minutes, the intensity of exercise was 60 to 80 percent of maximum heart rate).

Category

Behavior

3

Description

Aerobic exercise with 25-Hydroxy Vitamin D3 supplementation group: This group, In addition of Exercise Performance for 8 weeks (3sessions in week, each session 60-75 minutes, the intensity of exercise was 60 to 80 percent of maximum heart rate), will be receive 25-Hydroxy Vitamin D3 with dose 50000 units, One tablet per week for 8 weeks

Category

Treatment - Drugs

4

Description

Supplemented groups: this group will be receive 25-Hydroxy Vitamin D3 with dose 50000 units, One tablet per week for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Jesus, Son of Mary Hospital in Isfahan

Full name of responsible person

Naser Rahimi

Street address

Shams Abade Avenue, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan, Vice chancellor for research of Bu Ali Sina University

Full name of responsible person

Mohamad Ali Samavati Sharif

Street address

Vice chancellor for research, Bu Ali Sina University, Bu Ali Sina University, Pajuhesh Square, Hamedan

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan, Vice chancellor for research of Bu Ali Sina University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Bu Ali Sina University, Hamedan

Full name of responsible person

Naesr Rahimi

Position

Master's, PH.D Student, Exercise Physiology

Other areas of specialty/work

Street address

School of Physical Education and Sport Sciences, Hamedan University, Pajuhesh Square, Hamedan

City

Hamedan

Postal code

Phone

+98 31 3612 2649

Fax

Email

n.rahimi2009@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bu Ali Sina University, Hamedan

Full name of responsible person

Naser Rahimi

Position

Master's, PH.D Student, Exercise Physiology

Other areas of specialty/work**Street address**

School of Physical Education and Sport Sciences,
Hamedan University, Pajuhesh Square, Hamedan

City

Hamedan

Postal code**Phone**

+98 36122649

Fax**Email**

n.rahimi2009@yahoo.com

Web page address**Position**

Master's, PH.D Student, Exercise Physiology

Other areas of specialty/work**Street address**

School of Physical Education and Sport Sciences,
Hamedan University, Pajuhesh Square, Hamedan

City

Hamedan

Postal code**Phone**

+98 31 3612 2649

Fax**Email**

n.rahimi2009@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Bu Ali Sina University, Hamedan

Full name of responsible person

Naser Rahimi