

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Investigating the Effect of Aerobic Walking on Treadmill with Positive and Negative Slope on Serum Nitric Oxide Level of Type 2 Diabetic Patients

Protocol summary

Study aim

Investigating the Effect of Aerobic Training on Serum Nitric Oxide Level of Type 2 Diabetic Patients

Design

In this study, we will have two intervention group and a control group that will be identical. The sample size of each group will be at least 11, and the applicants will be randomly divided into two groups using the dice roll method.

Settings and conduct

At first, type 2 diabetic patients will enter the study according to the inclusion and exclusion criteria, and after primary assessments, they will be divided into first intervention, second intervention and control groups. The intervention groups will receive 12 sessions of intervention and then they will be evaluated and compared with the primary results and other groups. the location of the project will be in Karaj.

Participants/Inclusion and exclusion criteria

Type 2 diabetic patients with at least 5 years disease duration Age between 40-60 years HbA1C is higher than 7% Do not take NO-releasing drugs Ability to walk without any walking aids Blood pressure is higher than 140/90 mm Hg Patients who smoke, smoke hookah and drink alcohol. Neurological diseases, orthopedic lesions, retinopathy, foot ulcer, renal failure, liver failure, respiratory failure, cardiac failure, and thyroid failure Patients with venous thrombosis.

Intervention groups

The intervention groups will have 12 sessions of 20 minutes of walking on a treadmill with a slope of 5 degrees, and the control group will not receive any intervention.

Main outcome variables

Changes in the plasma nitric oxide level before and after exercises

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043299N3**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **prospective**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Seyed Ahmad Bagherian

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 3207

Email address

a.bagherian@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-09-07, 1399/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Aerobic Walking on Treadmill with Positive and Negative Slope on Serum Nitric Oxide Level of Type 2 Diabetic Patients

Public title

Investigating the Effect of Aerobic Training on Serum Nitric Oxide Level of Type 2 Diabetic Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 2 diabetic patients with at least 5 years disease duration Age between 40-60 years HbA1C is higher than 7% Do not take NO-releasing drugs Ability to walk without any walking aids

Exclusion criteria:

Blood pressure is higher than 140/90 mm Hg Patients who smoke, smoke hookah and drink alcohol. Neurological diseases, orthopedic lesions, retinopathy, foot ulcer, renal failure, liver failure, respiratory failure, cardiac failure, and thyroid failure Patients with venous thrombosis.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

The dice roll method will be used to randomize the grouping. So that the numbers 1 and 2 for the first intervention group and the numbers 3 and 4 for the second intervention group and the numbers 5 and 6 will be for the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Committee of Ethics in Research at Tarbiat Modares university

Street address

Tarbiat Modares University, Jalal-Al-Ahmad St.

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2013-11-30, 1392/09/09

Ethics committee reference number

۵۲/۴۸۳۶۵

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

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Changes in the plasma nitric oxide level before and after exercises

Timepoint

Before and after the first training session and after the end of the twelfth training session

Method of measurement

By blood test

Secondary outcomes

empty

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

First intervention group: Applicants walk on a treadmill with a positive slope of 5 degrees for 12 sessions and 20 minutes each session. The intensity of the exercises is considered to be 65-75% of the maximum heart rate.

Category

Treatment - Other

2**Description**

Control group: They will not receive any intervention.

Category

N/A

3

Description

Second intervention group: Applicants walk on a treadmill with a negative slope of 5 degrees for 12 sessions and 20 minutes each session. The intensity of the exercises is considered to be 65-75% of the maximum heart rate.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mahdi Dehghani specialized clinic

Full name of responsible person

Mahdi Dehghani Mohammad Abadi

Street address

Unit 15, 4th floor, Noor Doctors Building, next to City Book Building, Shahid Beheshti St.

City

Karaj

Province

Alborz

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Phone

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mehdidehghani52@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Yaaghoub Fath Allahi

Street address

The University of Tarbiat Modares, Jalal-Al-Ahmad St.

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Res@modares.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Seyed Ahmad Bagherian

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Tarbiat Modares

Full name of responsible person

Farid Bahrpeyma

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Seyed Ahmad Bagherian

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All information can be shared after making the subjects unidentifiable.

When the data will become available and for how long

6 months after publication of results

To whom data/document is available

All individuals can use information about the results of the study.

Under which criteria data/document could be used

To treat diabetic patients and to carry out new research in this field, data can be used with unidentifying individuals of the study.

From where data/document is obtainable

They can contact the researcher by email They can meet the Physical Therapy Department of Tarbiat Modares University

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

The requestor should explain the cause of the need for the data clearly and if the reasons are convincing, the data will be available to him.

Comments