

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The Effect of Aerobic Training on Level of Serum Troponin I , CK-MB ,Glycemic Indices and Lipid Profile in Type 2 Diabetes Women

Protocol summary

Study aim

The aim of this study was to evaluate the effect of aerobic exercise on serum levels of troponin I, creatine kinase MB and glycemic index and fat profile in women with type 2 diabetes.

Design

Clinical trial has two groups (control and intervention), one blind, simple randomization on 30 diabetic

Settings and conduct

The present study was performed on the effect of exercise on cardiac indices, glycemic index and fat profile in Najafabad city with 30 women with type 2 diabetes aged 30 to 50 years randomly selected. The method of blinding is a blind spot. Information that can distort the test result is hidden from the participant, but only the researcher is aware of it. Including: type of intervention, training protocol, sampling method and grouping method. Groups included: experimental group of 15 diabetic women participating in aerobic exercise and control group including: 15 diabetic women who did not have any regular exercise. Intervention: Aerobic exercises performed for 8 weeks, 3 (sessions per week). Moderate-intensity aerobic exercise, including walking, was performed at 55 to 75 percent of maximum heart rate.

Participants/Inclusion and exclusion criteria

Diabetic women 30 to 50 years old Type 2 diabetic. Having diabetes more than three years, treated only with oral medications and non insulin injections, etc. not having Sports Activity regular physical, at least the last 6 months and lacks any disease affecting. Lack of smoking, alcohol, caffeine and medicine. Not having heart disease and blood pressure.

Intervention groups

The experimental group consisted of 15 diabetic women participating in moderate intensity aerobic exercises and the control group consisted of 15 diabetic women who had no regular exercise activities.

Main outcome variables

Changes in fasting blood sugar, glycosylated hemoglobin, troponin I CK-MB, and lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200803048287N1**

Registration date: **2020-09-28, 1399/07/07**

Registration timing: **retrospective**

Last update: **2020-09-28, 1399/07/07**

Update count: **0**

Registration date

2020-09-28, 1399/07/07

Registrant information

Name

Batol Amini Najafabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4264 7809

Email address

amini12445522@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

2019-11-28, 1398/09/07

Actual recruitment end date

2019-12-25, 1398/10/04

Trial completion date

2020-02-27, 1398/12/08

Scientific title

The Effect of Aerobic Training on Level of Serum Troponin I , CK-MB ,Glycemic Indices and Lipid Profile in Type 2 Diabetes Women

Public title

Effect of Exercise on Heart, Blood sugar and Lipid Profile

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Being in the Age Range of 50 to 30 Years. Diabetes was Based on the Criteria of the World Health Organization. Having Diabetes more than Three Years. Treatment only with Medicines Edible and non Insulin Injections not having Sports Activity Regular Physical, at Least the Last 6 Months Not affecting any of the diseases (including history of cardiovascular disease, history of heart surgery) on research variables No smoking, alcohol, caffeine

Exclusion criteria:

History of cardiovascular disease, history of heart surgery Have regular physical activity for at least the last 6 months

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **18**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is used to assign samples to each group. For this purpose, we use random allocation software and select the block allocation method. The software categorizes numbers into two groups by assigning them to people. The researcher then divides the people into two groups according to the output list. Random allocation software was used for this purpose. In the software we specify the number of blocks (2 blocks) then the software gives us a list that randomly, the samples are assigned to two groups. Samples are selected based on that.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants in each group did not know about other people and their treatment plan. People in each group are called in for tests on different days. Also, the clinical caregiver who is responsible for recording

test results and clinical descriptions does not know which group this person belongs to. In addition, the data is entered in such a way that the treatment and control groups are marked with letters. The statistician cannot be informed about the group of people during the analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Groups included: Experimental or intervention group: 15 diabetic women participating in moderate-intensity aerobic exercise and control group: 15 diabetic women who did not engage in regular exercise. Interventions: The subjects in the control group did not do any exercise. In the intervention group, the exercise program included aerobic exercises that were performed for 8 weeks, 3 (sessions per week). Moderate-intensity aerobic exercise, including walking, was performed at 55 to 75 percent of maximum heart rate.

Secondary Ids

empty

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

Ethics Committee in Islamic Azad University- Najafabad Branch

Street address

No. 3/22, Shadan dead end, Shahram alley, Amirkabir street,

City

Najaf Abad

Province

Isfahan

Postal code

8514763493

Approval date

2020-09-09, 1399/06/19

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1399.083

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

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Troponin I

Timepoint

To measure troponin I in 3 times: 1- Pre-test 2- Six hours after the first exercise 3- Six hours after the last exercise session.

Method of measurement

Troponin I was measured using a monobind kit and Dynex device and Eliza method. The normal range in this method is up to 0.3 ng / ml.

2

Description

Creatine Kinase MB

Timepoint

In 3 times: 1- Pre-test 2- Twelve hours after the first training session 3- Twelve hours after the last training session.

Method of measurement

Immuno inhibition was performed using the Biosystem kit and the BA400 autoanalyzer. The normal range in this method is up to 24 U / L.

3

Description

Fasting blood sugar

Timepoint

After 12 hours of overnight fasting in the pre-test, and in the post-test (48 hours after the last training session)

Method of measurement

Glucose Oxidase was performed using Biosystem kit and BA400 autoanalyzer.

4

Description

Glycosylated hemoglobin A1C

Timepoint

After 12 hours of overnight fasting in the pre-test, and in the post-test (48 hours after the last training session)

Method of measurement

Immuno turbid metric was performed using Axzshzld kit and BA400 autoanalyzer.

5

Description

Fat profile (lipid profile)

Timepoint

After 12 hours of overnight fasting in the pre-test, and in the post-test (48 hours after the last training session)

Method of measurement

It was performed using the biosystem company kit and with BA400 autoanalyzer and peroxidase method.

Secondary outcomes

1

Description

Troponin I

Timepoint

To measure troponin I in 3 times: 1- Pre-test 2- Six hours after the first exercise 3- Six hours after the last exercise session.

Method of measurement

Troponin I was measured using a monobind kit and Dynex device and Eliza method. The normal range in this method is up to 0.3 ng / ml.

2

Description

Creatine Kinase MB

Timepoint

To measure CK-MB in 3 times: 1- Pre-test 2- Twelve hours after the first training session 3- Twelve hours after the last session

Method of measurement

CK-MB was measured using Biosystem kit and BA400 autoanalyzer by Immuno inhibition method. The normal range in this method is up to 24 U / L.

Intervention groups

1

Description

Intervention group: 15 diabetic women participating in moderate intensity aerobic exercise. Intervention: Exercise program including aerobic exercise that was performed for 8 weeks, 3 (sessions per week). Moderate-intensity aerobic exercise, including walking, was performed at 55 to 75 percent of maximum heart rate. These exercises were performed for 150 minutes per week and each session lasted 50 minutes. The warm-up program included 10 minutes of warm-up in the form of jogging, combined arm and leg movements, and stretching exercises. Performing aerobic exercises, the first two weeks 35 and once every two weeks, observing the principle of gradual overload, 5 minutes were added to the training time, and when returning to the initial state, 10 minutes of cooling movements were allocated. Exercises were performed in a gym at a temperature of 25 degrees Celsius

Category

Lifestyle

2

Description

Control group: 15 diabetic women who did not have any regular exercise.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Janan Diabetes Center in Najafabad

Full name of responsible person

Ayub Shapoori

Street address

Opposite Shahid Anari Alley, Danesh St., Shariati St.

City

Najafabad

Province

Isfahan

Postal code

8513794791

Phone

+98 31 4246 0640

Email

janan.ansar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The organization has not supported

Full name of responsible person

Batool Amini Najafabadi

Street address

No. 22/3, Shadan dead end, Shahram alley, Amirkabir street

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Email

amini12445522@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

The organization has not supported

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Education Najafabad

Full name of responsible person

Batool Amini Najafabadi

Position

Secretary of Education

Latest degree

Master

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Education Najafabad

Full name of responsible person

Batool Amini Najafabadi

Position

Secretary of Education Najafabad

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Other areas of specialty/work

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Person responsible for updating data

Contact

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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