Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 alloc ation 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 aliocation 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
Isfehan

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
Isfehan

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

City
Najafabad

Province
Isfehan

Postal code
8514763493

Phone
+98 31 4264 7809

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

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

City
Najafabad

Province
Isfehan

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Phone
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Email
amini12445522@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Education Najafabad

Full name of responsible person
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Position
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Email
amini12445522@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Education Najafabad

Full name of responsible person
Batool Amini Najafabadi

Position
Secretary of Education Najafabad
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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