

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of aerobic and resistance and combined exercise on the expression of mir-15a, muscular strength and endurance in women with type 2 diabetes.

Protocol summary

Study aim

1- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on miRNA-15a expression in women with type 2 diabetes 2- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on insulin resistance levels in women with type 2 diabetes 3- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on muscle strength and endurance in women with type 2 diabetes 4- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on insulin in women with type 2 diabetes 5- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on cardiorespiratory endurance in women with type 2 diabetes 6- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on body fat percentage in women with type 2 diabetes 7- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on glycosylated hemoglobin levels in women with type 2 diabetes

Design

Control group: having a normal lifestyle, aerobic, resistance and combined exercise (simultaneous aerobic and resistance exercise intervention)

Settings and conduct

These exercises are performed under the supervision of a sports specialist at the Sedighe Tahereh Endocrinology and Metabolism Research Center.

Participants/Inclusion and exclusion criteria

Type 2 diabetes, failure to participate in regular physical activities over the past year, normal diabetic foot , no chest pain , no history of hospitalization, normal foot pulse, no history of diabetic foot ulcers, no history of retinal hemorrhage and Avastin injection

Intervention groups

Aerobic exercises, resistance exercises, combined

exercises, control

Main outcome variables

Improve strength, endurance, disease status, cardiorespiratory endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240721062487N2**

Registration date: **2025-02-27, 1403/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2025-02-27, 1403/12/09**

Update count: **0**

Registration date

2025-02-27, 1403/12/09

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-19, 1403/12/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic and resistance and combined exercise on the expression of mir-15a, muscular strength and endurance in women with type 2 diabetes.

Public title

Exercise training and type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Gender: Female Aged between 30-60 years Not participating in regular physical activity Not using drugs Not using insulin injections Normal examination of the diabetic foot Not chest pain or heaviness or history of hospitalization for heart disease Not history of retinal bleeding and Avastin injection(No history of Proliferative retinopathy) No other underlying disease

Exclusion criteria:

Voluntary withdrawal of participants from continuing the study Having a specific illness that prevents physical activity Occurrence of physical injury Absence of more than three session in sports interventions Pregnancy

AgeFrom **40 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Initially, participants are evaluated and ranked according to factors such as muscle strength or endurance and cardiovascular endurance, and subsequently categorized into two groups based on their preferences for specific types of exercise.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants dose not know of their group assignment. The researcher does not know which group each individual is in. The clinical monitor does not know each participant's group assignment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Isfahan University of Medical Sciences - Alzahra Research Centers Complex

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Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town

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Approval date

2025-02-19, 1403/12/01

Ethics committee reference number

IR.ARI.MUI.REC.1403.244

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

Type 2 diabetes mellitus

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

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

miRNA-15a, FBS, HDL, LDL, CREATININE, Muscle endurance and strength

Timepoint

48 hours before intervention, after intervention for 2 months

Method of measurement

Blood sampling, Dynamometer, Fitness tests

Secondary outcomes

empty

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

Control group: Having a normal life routine within 8 weeks
Category
Lifestyle

2

Description
Intervention group: Performing aerobic exercise
Category
Lifestyle

3

Description
Intervention group: Performing endurance exercise
Category
Lifestyle

4

Description
Intervention group: Performing combined exercise
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
10
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

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It can be available upon request from academic researchers, in coordination with the university's Vice President for Research.

When the data will become available and for how long

Three months after publication, the article can be made available at the discretion of the corresponding author and the university's vice president for research.

To whom data/document is available

Only academic researchers can access this information.

Under which criteria data/document could be used

The use of data for statistical analysis and inferential statistics is not permitted.

From where data/document is obtainable

First, coordination must be made with the university's vice president for research and then with the corresponding author.

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

Official request to the Vice President for Research of the university, administrative correspondence from the Vice President for Research to the corresponding author

Comments