

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of aerobic exercise type on cardiac inflammatory markers in women with type 2 diabetes

Protocol summary

Study aim

The effect of aerobic exercise on cardiac inflammatory markers in women with type 2 diabetes

Design

In this study, 36 participants will be randomly divided into 3 groups: high intensity intermittent training, moderate intensity continuous training and control group. Clinical trial work with parallel groups

Settings and conduct

The subjects of this study will be selected from the patients of Tehran Diabetes Clinic and the training program will be performed in the rehabilitation center of this center. Blood sampling will also be performed in the laboratory of this center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with type 2 diabetes, according to the diagnosis of a doctor who has been diagnosed with the disease for at least 3 years, had no change in the use of antihypertensive drugs, blood lipids and blood pressure in the last two months and blood pressure should not exceed 160.95 mm Hg.

Intervention groups

1-high intense intermittent training group (12 people). 2-Medium intensity continuous training group (12 people). 3- Control group (12 people without training)

Main outcome variables

Cardiotrophin 1; Pentraxine 3; Galactin 3; Interleukin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200729048252N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **retrospective**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Masoumeh Gholaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4414 4738

Email address

masoumeh.gholaman@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-02, 1399/02/13

Expected recruitment end date

2020-07-03, 1399/04/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic exercise type on cardiac inflammatory markers in women with type 2 diabetes

Public title

The effect of aerobic exercise on cardiac inflammatory factors in diabetic women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women in the age range of 35 to 50 years They develop

type 2 diabetes by measuring their fasting glucose twice (mean above 125 mg / dL) and having it approved by a doctor. Body mass index higher than 25 and less than 30 kg / m2 Lack of cardiovascular disease Lack of regular physical exercise in the last year No restrictions or physical problems to participate in the training program

Exclusion criteria:

Failure to sign informed written consent Smoking and alcohol at least once a week Pregnancy and lactation Menopause Hyper tension Liver and kidney failure

Age

From **35 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Thirty-six diabetic patients are randomly divided into three groups of 12 through a random number table. The first and second groups are selected as the intervention group and the third group is selected as 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

Ethics Committee of Islamic Azad University,
Research Sciences Branch

Street address

Shohada Hesarak Boulevard, University Square, Ehsan
end of Shahid Sattari Highway

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2020-06-24, 1399/04/04

Ethics committee reference number

IR.IAU.SRB.REC.1399.011

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

Pentraxine 3

Timepoint

Before training protocols and 12 weeks later (after training protocols are completed)

Method of measurement

Using the ELISA laboratory kit

2

Description

Cardiotrophin 1

Timepoint

Before training protocols and 12 weeks later (after training protocols are completed)

Method of measurement

Using the ELISA laboratory kit

3

Description

Galactin 3

Timepoint

Before training protocols and 12 weeks later (after training protocols are completed)

Method of measurement

Using the ELISA laboratory kit

4

Description

Interleukin 6

Timepoint

Before training protocols and 12 weeks later (after training protocols are completed)

Method of measurement

Using the ELISA laboratory kit

Secondary outcomes

1

Description

Glucose

Timepoint

Before training protocols and 12 weeks later (after training protocols are completed)

Method of measurement
Pars Azmoun Company Kit

2

Description

Insulin

Timepoint

Before training protocols and 12 weeks later (after training protocols are completed)

Method of measurement

Insulin ELISA Kit

3

Description

Insulin resistance

Timepoint

Before training protocols and 12 weeks later (after training protocols are completed)

Method of measurement

Evaluation of homeostasis model (HOMA-IR)

Intervention groups

1

Description

The first intervention group (high-intensity interval training): consists of 10 minutes of warm-up with an intensity of 50-60% of the maximum heart rate, followed by four intense four-minute intervals with an intensity of 90% of the maximum heart rate, and after At each intense alternation, subjects take three minutes of active rest at 50-60% of their maximum heart rate. This training program is performed for 12 weeks and three sessions per week.

Category

Prevention

2

Description

The second intervention group (moderate intensity continuous training): consists of 10 minutes of warm-up with an intensity of 50-60% of the maximum heart rate. Subsequently, continuous training is performed for 47 minutes and with an intensity of 70-60% of the maximum heart rate. This training program is performed for 12 weeks and three sessions per week.

Category

Prevention

3

Description

Control group: The subjects in the control group continue their usual daily program and do not participate in any regular physical training program until the end of the research.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Diabetes Clinic

Full name of responsible person

Maryam Pourabbas

Street address

Tehran Diabetes Clinic, Hayat Crossroads, Shahrivar West Ave., North Kargar Ave.

City

Tehran

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Tehran

Postal code

1411713135

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+98 21 8833 4190

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shilamontazer@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sina Forouzeh

Street address

University of scientific research, Shohada Hesarak Boulevard, University Square , The end of Shahid Sattari Highway

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Phone

+98 21 4486 9827

Email

Basic-fa@srbiau.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Research Assistant, Islamic Azad University - Research Sciences Branch

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoumeh Gholaman

Position

PhD Student

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

Street address

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Boulevard, Shahrziba

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data after unidentifiable individuals

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Participants in the study can learn about the results and documents in detail to find out how the protocols affect their disease conditions so that they can use the protocols if they are useful. Researchers can also use the results in similar studies access documents. People working in rehabilitation departments to perform registered protocols for diabetics can also from use documentation and protocol.

From where data/document is obtainable

Send your request to the following email address .

Masoumeh.gholaman@gmail .com

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

People requesting an email with the subject of the request to the address .They will send a form for them as soon as they receive it.Will post the profile of the people

and the reason for their request in this the form will be registered after completing the form and resending the form to the item email comments on the documents will be provided as a pdf file.

Comments