Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ofantihypertensive 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
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Iran (Islamic Republic of)
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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 tention 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, Ehe 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 complet

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 rat.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
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1411713135
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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

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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