

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effect of eight weeks of intense and continuous periodic exercises on plasma levels of myeloperoxidase in type 2 diabetic patients

Protocol summary

Study aim

Overall Objective: The effect of eight weeks of intense and continuous periodic exercises on plasma levels of myeloperoxidase in diabetic type 2

Design

30 Type 2 diabetic patients with a randomized configuration will be divided into three groups of control, periodic exercises and continuous training. How to randomize through the numbers table.

Settings and conduct

This research will be carried out in the rehabilitation department of Tehran's Shahid Rajaee Heart Hospital. Except for the researcher, none of the participants will be informed about how to assign individuals in different groups.

Participants/Inclusion and exclusion criteria

Type 2 diabetic patients aged 35 to 60 years with a BMI of 25 to 35 kilogram/ m² will be included in this study. Individuals with cardiovascular disease, kidney and kidney problems, pulmonary disease, Cancer, gout, or orthopedic constraints will be eliminated. Also, subjects should not take any sporting activity two or three months before the protocol commences.

Intervention groups

Control group (n = 10), severe periodic exercise group (n = 10), continuous training group (n = 10).

Main outcome variables

In general, the purpose of this exercise is to reduce the inflammatory factor of myeloperoxidase in type 2 diabetic patients and to slow down the progression of the disease and the complications of the disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181219042055N1**

Registration date: **2019-02-17, 1397/11/28**

Registration timing: **retrospective**

Last update: **2019-02-17, 1397/11/28**

Update count: **0**

Registration date

2019-02-17, 1397/11/28

Registrant information

Name

Sara Lotfian

Name of organization / entity

Shaheed Rajaee Heart Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2489

Email address

lotfian.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-28, 1397/10/07

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of eight weeks of intense and continuous periodic exercises on plasma levels of

myeloperoxidase in type 2 diabetic patients

Public title

The effect of two types of aerobic exercise on inflammatory factors in diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

People with type 2 diabetes Age range 35 to 60 years
Body mass is between 25 and 35 kg / m²

Exclusion criteria:

People with cardiovascular disease People with pulmonary disease
People with pulmonary disease smokers Alcoholic people People who have gout or orthopedic restrictions

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Tool: Randomization Tool: Like a random number table, a stacked envelope, a statistical software of the lottery method was used after the sample size was determined. For each member of the community, we assigned a code or number, and it was written on cardboard and poured into a bag, and then one out of the bag.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is done in trivial blinds and the only researcher knows how to assign individuals to different groups. In general, all participants in this project are unaware of what kind of sports group they have been told, and the researcher will individually give the exercises to individuals, and no explanation will be given about the type and name of the exercise. The only workout style that is aerobic and will be done on the treadmill will be notified to individuals. In data analyzers, clinical care, outcome evaluators, as well as safety committees and data monitoring, there will be no information about how to assign exercises.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Educational Center, Shahid Rajaei Cardiology Research Research Center

Street address

Valiasr Ave., Intersection of the prayer center of Shahid Rajaei Cardiology Research Center

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2018-09-29, 1397/07/07

Ethics committee reference number

IR.RHC.REC.1397.048

Health conditions studied

1

Description of health condition studied

Type 2 diabetes patients

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

plasma levels of Myeloperoxidase

Timepoint

Before starting the training protocols and 8 weeks later (after completing the practice protocols)

Method of measurement

blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: An intense periodic exercise group that performs aerobic training for 8 weeks and 3 sessions per week.

Category

Prevention

2

Description

Intervention group: The continuous training group will conduct aerobic training sessions for 8 weeks and 3 sessions per week.

Category

Diagnosis

3

Description

The control group is not given any training

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

sara lotfiyan

Street address

Valiasr St., Intersection of Prayer, Research Center for Heart and Shahid Rajaei Heart Therapy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Treatment Center for Sshahid Rajaei Heart and Heart Research Center

Full name of responsible person

sara lotfiyan

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Valiasr Street, next to Mellat Park - Nabash Nayesh, Shahid Rajaei Heart and Heart Research and Treatment Research Center

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Grant name

The author of the project, Dr. Mohsen Adandi, is from Semnan University and some of the funding for this project will be from their Grant.

Grant code / Reference number

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

No

Title of funding source

Semnan University

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

Academic

2

Sponsor

Name of organization / entity

Shahid Rajaei Cardiology Research and Treatment Center

Full name of responsible person

Dr. Majid Maleki

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Rajaei Cardiology Research and Treatment Center

Proportion provided by this source

100

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

Person responsible for general inquiries**Contact****Name of organization / entity**Research center for cardiovascular and cardiology
research of Shahid Rajaei**Full name of responsible person**

sara lotfiyan

Position

Faculty member

Latest degree

Specialist

Other areas of specialty/work

Sports medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University

Full name of responsible person

Mohsen Avandi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport physiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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Web page address**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/documentIn this study, the personal information of the participants
in the project, such as age range, height range, weight
range, BMI range, individuals will be published as a
table. Also, after completing the protocol, the result of the
effect of different protocols. It will also be noted on
specified factors as well as factors such as insulin
resistance and H₁C will also be published.**When the data will become available and for how long**

Access time since 1398

To whom data/document is availableAll participants in this project can get results if they so
wish. Also, all diabetics at the Shahid Rajaei Cardiology
and Semnan University can access the results of this
project. People working in the rehabilitation departments

of Rajae Hospital.

Under which criteria data/document could be used

Participants in the study and diabetics at Shahid Rajae Hospital, and in order to know how the protocols affect the conditions of their illness, they can be informed of the results and documentation so that they can be used if the protocols are useful. Also, researchers can access the documentation to use the results in similar research. People working in rehab groups can also use documentation and protocols to conduct protocols for diabetics.

From where data/document is obtainable

Individuals can send their requests to the following email addresses:mohsenavandi@gmail.com

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

Individuals requesting an email with an incident request will send their addresses to them. Upon receipt of the email, a form will be sent to them, specifying the individuals and the reason they will be required to register on this form after completing the form and resubmitting. The form will be submitted to the pdf file by email.

Comments