Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparisons effect of eight weeks high intensity interval training (HIIT) and continuous moderate training (CMT) on plasma levels of Calprotectin and IL-6 in type 2 diabetic persons

Protocol summary

Study aim

General purpose: Investigation of the Effect of eight weeks HIIT and CMT on plasma levels of Calprotectin and IL-6 in type 2 diabetic persons Detailed goals : 1. Investigation of the Effect of eight weeks HIIT on plasma levels of Calprotectin in type 2 diabetic persons 2. Investigation of the Effect of eight weeks CMT on plasma levels of Calprotectin in type 2 diabetic persons 3. Investigation of the Effect of eight weeks HIIT on plasma levels of IL-6 in type 2 diabetic persons 4. Investigation of the Effect of eight weeks CMT on plasma levels of IL-6 in type 2 diabetic persons 5. Compare the effects of eight weeks HIIT and CMT on plasma levels of Calprotectin and IL-6 in type 2 diabetic persons

Design

30 type 2 diabetic subjects will be divided into three groups: control, HIIT and CMT. The randomization method will be through the number table.

Settings and conduct

This research will be done in the rehabilitation department of Shahid Rajaee Hospital. Other than the researcher, none of the participants in this study will know how to assign individuals in different groups.

Participants/Inclusion and exclusion criteria

This research will have thirty type 2 diabetic people with the age of 35 to 60 and body mass between 25 to 35 kilogram / square meter as an available sample.People with cardiovascular disease, kidney and liver problems, pulmonary disease, cancer, gout, or orthopedic restrictions will be deleted. Also, subjects should not take any sporting activities two or three months before the start of the protocol

Intervention groups

control group (N=10), high intensity interval training group (N=10), and continuous moderate training (CMT) group (N=10)

Main outcome variables

In general, the purpose of this exercise is to reduce inflammatory factors 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: **IRCT20181129041797N1**
Registration date: **2018-12-25, 1397/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-25, 1397/10/04**
Update count: **0**

Registration date

2018-12-25, 1397/10/04

Registrant information

Name

Zahra Ghaemmaghami

Name of organization / entity

Shahid Rajaie Cardiovascular, Medical & Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisons effect of eight weeks high intensity interval training (HIIT) and continuous moderate training (CMT) on plasma levels of Calprotectin and IL-6 in type 2 diabetic persons

Public title

The effect of two types of aerobic exercise on inflammatory factors in type 2 diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes Body mass is between 25 and 35 kg / m 2 Age range 35 to 60 years

Exclusion criteria:

People with cardiovascular disease People who have kidney and liver problems People with pulmonary disease People who have gout or orthopedic restrictions smokers Alcoholics

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization tool: such as random numbered table, Sealed envelope, statistical software

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is done triple blind 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 are said to be, and the researcher will individually give the exercises to individuals and will not be explained to people about the type and name of the exercise. Only the type of exercises that are aerobic on a treadmill will be provided to individuals. In fact, the data analyst, clinical caregiver, outcome assessor, as well as the safety committee and data monitoring will not know 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 of the Shahid Rajaee Cardiology Research Center

Street address

Shahid Rajaee Cardiology Research Center, Intersection of Niayesh, Valiasr street

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2018-09-29, 1397/07/07

Ethics committee reference number

IR.RHC.REC.1397.049

Health conditions studied

1

Description of health condition studied

Type 2 diabetic patients

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Plasma levels of Calprotectin

Timepoint

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

Method of measurement

blood sampling

2

Description

plasma levels of IL-6

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 group1:High intensity interval training that performs interval aerobic training for 8 weeks and 3 sessions per week.
Category
Diagnosis

2

Description
Intervention group 2: Continuous moderate training that will performs continuous aerobic exercise for 8 weeks and 3 sessions a week
Category
Diagnosis

3

Description
Control group: The control group is not given any training
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان شهید رجایی
Full name of responsible person
Zahra ghaemmaghami
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2

Recruitment center
Name of recruitment center
Diabetes Research Center, Endocrinology and Metabolism Research Institute University of Tehran
Full name of responsible person
camelia Rambod
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Rajaee Cardiovascular Research and Treatment Center
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Grant name
Corresponding author, Dr. Mohsen Avandi, will be 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
Persons

2

Sponsor

Name of organization / entity
Shahid Rajaee Cardiovascular Research and Treatment Center

Full name of responsible person
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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 Rajaee Cardiovascular 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
Shahid Rajaee Cardiovascular Research and Treatment Center

Full name of responsible person
Zahra ghaemmaghami

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Endocrinologist

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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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

In this study, the personal information of the participants in the project, such as age range, height range, weight range, BMI range, will be published as a table. Also, upon completion of the protocol, the result of the effect of the protocol on the specified factors, Insulin resistance and HA1c will also be published.

When the data will become available and for how long

Access time since 1398

To whom data/document is available

All participants in this project can be informed on request if they so request. Also, all diabetics at the Shahid Rajaee Cardiology and Heart Disease Hospital, Tehran University of Medical Sciences and Semnan University can access the results of this project. Researchers at different universities.People who working in hospital rehab centers.It is important to point that people outside the project, at academic levels with the reason for the request, can get results if they are interested.

Under which criteria data/document could be used

Participants in the study and diabetics at Shahid Rajaee Hospital and Tehran University of Medical Sciences Diabetes Clinic To know how the protocols affect the conditions of their disease, they can inform the results and documentation so that they can be used if the protocols are useful. Researchers also access documents in order to use results in similar research. People working in rehab groups can also use documentation and protocols to perform protocols for diabetics.

From where data/document is obtainable

People can submit their requests to the following email addresses: mohsenavandi@gmail.com Z.ghaemmaghami@rhc.ac.ir rambod.camelia@gmail.com s.alizadeh@semnan.ac.ir

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

Applicants send an email with the subject of the request to the addresses provided. Upon receipt of the email, a form will be sent to them, specifying the individuals and the reason for their request will be recorded in this form after completing the form and re-submitting the form to The email documentation will be available as pdf files.

Comments