Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of eight weeks of high-intensity interval training (HIIT) on mir-27a and C-reactive protein levels in obese middle-aged men

Protocol summary

Study aim

The effect of eight weeks high intensity interval training on mir-27a expression and serum levels of C-reactive protein (CRP) in Middle-Aged Obese Men

Design

The clinical trial will consist of two groups. Twenty-four obese middle-aged men (voluntarily) will be divided into two groups of intervention (Interval training) and control (without intervention) with random arrangement (simple randomization). The present design will be a semi-experimental and single blind.

Settings and conduct

In a quasi-experimental research project, 24 obese middle-aged men (40 to 50 years old) were considered as a research sample. Subjects will be randomly divided into 2 groups of 12: control and High Intensity Interval Training (HIIT). The training protocol is performed 3-4 days a week for eight weeks. Blood samples are taken at rest 48 hours before the start of training and 48 hours after the last training session. All measurements and exercises will be measured in the Tabriz Technical and Vocational University.

Participants/Inclusion and exclusion criteria

inclusion criteria: obese middle-aged men aged 40 to 50 years, without cardio-respiratory problems, body mass index (BMI) above 30 (BMI>30), inactive (less than 90 minutes of regular exercise per week), no medication, and anabolic supplements, Blood pressure, anti-inflammatory, and antioxidant. exclusion criteria: Chronic diseases (such as cardiovascular disease, cancer or respiratory diseases), smoking and BMI<30.

Intervention groups

Two groups: 1- High Intensity Interval Training (HIIT) and 2- Control Group (will do nothing)

Main outcome variables

mir-27a and C-reactive protein (CRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220128053844N1**
Registration date: **2022-03-16, 1400/12/25**
Registration timing: **retrospective**

Last update: **2022-03-16, 1400/12/25**
Update count: **0**

Registration date

2022-03-16, 1400/12/25

Registrant information

Name

hamid reza zolfi

Name of organization / entity

Technical and vocational university

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 9011

Email address

hzolfi@tabrizu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of eight weeks of high-intensity interval training (HIIT) on mir-27a and C-reactive protein levels in obese middle-aged men

Public title
Effect of exercise training on obse men

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 40 to 50 years body mass index above 30

Exclusion criteria:
Smoking Blood sugar is above the normal range Blood lipids are above the normal range Taking certain medications to control body weight and blood pressure during the last three months Diastolic and systolic pressures greater than 100 and 140 mm Hg, respectively

Age
From **40 years** old to **50 years** old

Gender
Male

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: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Assigning samples using simple random-lottery method. In this method, first the list of names of all members is obtained. It is then assigned a number to each. It is placed inside the box. The papers are then selected and removed individually until the desired sample size is complete.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study is performed in a single blind manner and the only researchers 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 researchers will individually give the exercise to individuals and will not be explained to people about the type and name of the exercise. Also, the data analyst, clinical caregiver, outcome assessor, as well as the safety committee and data monitoring will not know how to assign exercise.

Placebo
Not used

Assignment
Parallel

Other design features
In the present study, participants were randomly assigned to two training and control groups. The control group does not receive any intervention (exercise or supplement). Blood samples are taken from the control group only in two time periods.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Sport Sciences Research Institute

Street address
No. 3-Fifth Alley - Mir Emad St-Ostad Motahhari St-Tehran

City
Tehran

Province
Tehran

Postal code
1587958711

Approval date
2021-11-21, 1400/08/30

Ethics committee reference number
IR.SSRC.REC.1400.109

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The level of micro RNA27-a

Timepoint
Before and after starting eight weeks of HIIT training

Method of measurement
Real-Time PCR and using PCR mic

2

Description
The level of C-Reactive Protein (CRP)

Timepoint
Before and after starting eight weeks of HIIT training

Method of measurement
It will be measured by Elisa Reader method with high sensitivity.

Secondary outcomes

1

Description
Blood sugar
Timepoint
Before and after the start of research
Method of measurement
Using the kit of Pars Azmoun company and with the sensitivity of the kit, 5 mg / dl will be measured.

2

Description
Lipid profile
Timepoint
Before and after the start of research
Method of measurement
The test will be measured by enzymatic calorimetric method and Pars Company kit.

Intervention groups

1

Description
Intervention group: Eight weeks of high-intensity interval training (HIIT). Subjects will participate in high-intensity interval training (HIIT) 3-4 days a week for 8 weeks. Blood samples are taken at rest 48 hours before the start of training and 48 hours after the last training session.
Category
Prevention

2

Description
Control group: They will not do anything
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Technical and vocational university
Full name of responsible person
Hamidreza zolfi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Technical and vocational university
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

Person responsible for general inquiries

Contact
Name of organization / entity
East Azarbaijan Technical and Vocational University.
Full name of responsible person
Hamid Reza Zolfi
Position
Assistant Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
In the meetings that will be held with the participants before and after the study, all the data and their analysis, consent and trial and study protocol will be explained to them.
When the data will become available and for how long
Depending on the variable, the data of some variables will be accessed before the start of the research and others after the end of the research.
To whom data/document is available
Project participants, researchers and university professors
Under which criteria data/document could be used
Other researchers will be allowed to access the data in order to use and assist other researchers and to commit not to misuse the data.
From where data/document is obtainable
Email - In-person visit
What processes are involved for a request to access data/document
Provide identification documents and research resume and provide commitment in order not to misuse the data
Comments