Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of 8 weeks of combined exercise training (aerobic-resistance) on microRNAs involved in pain, inflammation and fatigue in patients with MS.

Protocol summary

Study aim

The general purpose of this research is to investigate the effect of a combined exercise protocol (aerobic resistance) on microRNAs involved in pain, inflammation and fatigue in MS patients.

Design

First, we randomly divided 36 men and women with relapsing-remitting MS into control and exercise groups. The randomization method will be simple. Then the training group starts to do the training protocol for 8 weeks while the control group does not do any training during these 8 weeks.

Settings and conduct

The study site will be the MS Research Center of Sinai Hospital.

Participants/Inclusion and exclusion criteria

The main criteria for entering the research Male and female patients with MS with EDSS 1 to 4 Only patients using interferon-beta medication alone will participate in the study. Age range from 25 to 45 years Lack of regular physical activity in the last 6 months Ability to perform sports protocol The main criteria for exiting the research Worsening of the patient's condition Inability to complete the exercise protocol The beginning of the relapse period

Intervention groups

The intervention considered in this research is 8 weeks of combined sports training (aerobic-resistance) which only the training group will be able to do, and the control group will not have any sports activities during these 8 weeks.

Main outcome variables

The main variables considered in this research are micro RNAs involved in pain, inflammation and fatigue of MS patients, which will include miR-155, miR-326, miR-23b, miR146a. Also, the amount of pain, quality of sleep, quality of life, time to reach fatigue and EDSS score are other variables considered for measurement.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058515N1**
Registration date: **2023-07-04, 1402/04/13**
Registration timing: **prospective**

Last update: **2023-07-04, 1402/04/13**
Update count: **0**

Registration date

2023-07-04, 1402/04/13

Registrant information

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mohammad torab

Name of organization / entity

Tehran university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-08, 1402/04/17

Expected recruitment end date

2023-07-15, 1402/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of 8 weeks of combined exercise training (aerobic-resistance) on microRNAs involved in pain, inflammation and fatigue in patients with MS.

Public title
The effect of 8 weeks of combined exercise training (aerobic-resistance) on microRNAs involved in pain, inflammation and fatigue in patients with MS.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Male and female patients with MS with EDSS 1 to 4 Only patients using interferon-beta medication alone will participate in the study. Age range from 25 to 45 years Lack of regular physical activity in the last 6 months Ability to perform sports protocol
Exclusion criteria:
Worsening of the patient's condition Inability to complete the exercise protocol The beginning of the relapse period

Age
From **25 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization Randomization unit: individual The randomization method will be a coin toss. Usually, this method is used to create a random sequence in two-group experiments in such a way that one of the studied groups is considered a lion and the other group is considered a line, and based on the desired sample size, the same number of coins are thrown. and people are divided into two groups. They find it by accident.

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 Neuroscience Research Institute <<Neural Rehabilitation>>

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No. 2-4th West Dead End-Shahid Naqeibi Alley-Kamali St.-Tehran

City
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Province
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Postal code
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Approval date
2023-06-11, 1402/03/21

Ethics committee reference number
IR.TUMS.NI.REC.1402.006

Health conditions studied

1

Description of health condition studied
multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
miR-155 , miR-326, miR-23b, miR-146a

Timepoint
Before starting the training program and 24 hours after the last training session

Method of measurement
RT-PCR

Secondary outcomes

1

Description
Sleep quality

Timepoint
Before starting the training program and 24 hours after the last training session

Method of measurement
In order to measure the effect of the combined exercise program on the sleep quality of these patients, the Sleep Quality Questionnaire (PSQI) will be used.

2

Description
Quality of Life

Timepoint
Before the start of the training program and after the end of the training program

Method of measurement

In order to measure the effect of the combined exercise program on the quality of life of these patients, the quality of life questionnaire of MS patients (MSQOL-54) will be used.

3

Description
Fatigue rate
Timepoint
Before starting the training program and after it ends
Method of measurement
In order to measure the effect of the combined exercise program on the fatigue level of this patient, the comprehensive fatigue assessment scale in patients with MS (CFAB-MS) from the questionnaire related to fatigue in these patients will be used.

4

Description
The amount of pain
Timepoint
Before starting the training program and after it ends.
Method of measurement
The McGill Pain Questionnaire (SF-MPQ) will be used to measure the effect of the combined exercise program on the pain level of these patients.

5

Description
EDSS
Timepoint
Before starting the training program and after its termination
Method of measurement
by a neurologist

6

Description
Time to get tired
Timepoint
Before starting the training program and after its termination
Method of measurement
6 minute walk test

Intervention groups

1

Description
Intervention group: The intervention group (exercise) will be monitored for 8 weeks to start sports activities. In this way, two sessions of aerobic exercise per week using a stationary bike and two sessions per week of resistance exercise using bodybuilding machines are performed in the form of knee flexion and extension. Before starting the training program, all movements are closely taught to the returnees.
Category
Rehabilitation

2

Description
Control group: control The control group will avoid any planned and regular physical activity during the time that the training group is doing the activity.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Sinai Hospital MS Research Center
Full name of responsible person
Dr. Maryam Abolhasani
Street address
Sina Hospital- Narsideh to Hasan Abad Square- Imam Khomeini St.-Tehran
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Institute of Neuroscience, Faculty of Medical Sciences, Tehran
Full name of responsible person
Dr. Akbar Fatuhi
Street address
Reyhaneh Building - Imam Khomeini Hospital - End of Keshavarz Boulevard - Tehran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
No
Title of funding source
Sinai Hospital MS Research Center
Proportion provided by this source
10
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
Tehran university
Full name of responsible person
Mohammad Torab
Position
Student
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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
Yes - There is a plan to make this available
Title and more details about the data/document
After the completion of the research, all the data of this research will be published with full interpretation in the form of student thesis and scientific-research articles.
When the data will become available and for how long
It is expected that data related to this research will be available from February 1402.
To whom data/document is available
All researchers in the field of clinical sports physiology

and specialist doctors can access these data after the publication of articles from the project.

Under which criteria data/document could be used

The current research is an applied research and the data and protocol obtained from this plan are used to prevent the severity of the disease.

From where data/document is obtainable

To get the raw data, you can refer to the main researchers of this project (Mr. Mohammad Torab, Dr. Mohammad Reza Kordi, and Ms. Dr. Maryam Abolhasani).

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

In order to receive data, the researcher must submit an official request to the university and the research institute where he is working, in which it is clearly stated for what purpose he wants to use this data and whether this data is effective in advancing his research.

Comments