

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Name

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>>

Street address

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

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Tehran

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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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

Latest degree

Master

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

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