

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of eight weeks of combined training on the expression of some anti-antimicrobial and micro-RNAs related to immune, TLR-4 and TLR-2 in patients with multiple sclerosis

Protocol summary

Study aim

The effect of eight weeks of combined aerobic and resistance training on peptides expression, LL-37, beta-2nd human-2-, indices, TLR-2, TLR-4 and MicroRNA 155, 326, 23b, 21 and 146a in MS patients.

Design

his quasi-experimental study with pretest-posttest with experimental and control groups was used. After selecting 24 people, according to their inclusion criteria, random allocation will be divided into two groups of experimental and control.

Settings and conduct

The study population consisted of 90 of MS patient in Shahrekord, which 24 of them will be selected based on inclusion criteria. Then they will be randomly divided into two groups of experimental (n = 12) and control (n = 12). The study place will be conducted in Pars shahrekord Sports medicine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed diagnosis of relapsing and remitting MS; An Expanded Disability Status Scale (EDSS) score of 1 to 4; No history of any medical condition, that would preclude participation in the exercise program; Ability to participate in exercise; No participants in regular exercise in the last 6 months; The age range of 20-40. Non Inclusion criteria: Comorbidities that prevent participation (cardiovascular disease, metabolic disease, ets); Corticosteroid treatment; Body injury that effective cannot participate in the exercise program; Pregnancy.

Intervention groups

Experimental group: Combined Training (aerobic + resistance) for 8 weeks, 4 sessions with mild to moderate intensity will consist of 3 sessions of aerobic training and one session of resistance training. Control group: This group will not receive any intervention.

Main outcome variables

Relative expression LL-37; hDB-2; TLR-4; TLR-2 and

microRNAs 155; 326; 21; 23b;146a

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191006045004N1**

Registration date: **2019-11-15, 1398/08/24**

Registration timing: **retrospective**

Last update: **2019-11-15, 1398/08/24**

Update count: **0**

Registration date

2019-11-15, 1398/08/24

Registrant information

Name

Saman Yousefi saqqezi

Name of organization / entity

Shahrekord University

Country

Iran (Islamic Republic of)

Phone

+98 38 3225 4315

Email address

samanyousefi25@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2019-06-30, 1398/04/09

Actual recruitment start date

2019-06-30, 1398/04/09

Actual recruitment end date

2019-07-10, 1398/04/19
Trial completion date
 2019-09-12, 1398/06/21

Scientific title
 The effect of eight weeks of combined training on the expression of some anti-antimicrobial and micro-RNAS related to immune, TLR-4 and TLR-2 in patients with multiple sclerosis

Public title
 Effect of exercise on immune and inflammatory factors in MS patients

Purpose
 Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
 Confirmed diagnosis of definite relapsing and remitting MS (RRMS) An Expanded Disability Status Scale (EDSS) Score of 1 to 4 No history of any medical condition, that would preclude participation in the exercise program Ability to participate in exercise No Participants in regular exercise in the last 6 months The age range of 20 - 40 years
Exclusion criteria:
 Comorbidities that prevent participation (cardiovascular disease: metabolic disease: etc.) Corticosteroid treatment Body injury that they effectively cannot participate in the exercise program Pregnancy

Age
 From **20 years** old to **40 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **24**
 Actual sample size reached: **24**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Subjects will be selected based on the criteria for entering the study as well as other necessary examinations. Then, the subjects will be randomly assigned (simple lottery) to the experimental and control groups. The simple lottery method in this study is done first; the names of all the people in accordance with the inclusion criteria; without observing the specific order on the paper pieces and placed inside the box (A total; 24 of them will select). Then mix the paper and the first 12 numbers whose names came out of the box in the experimental group and the next 12 people will be placed in the control group.

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 in Research Sport Sciences
 Research Institute

Street address

No,3, 5th St., Mir Emad St., Motahari Ave., Tehran,
 Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2019-06-30, 1398/04/09

Ethics committee reference number

IR.SSRC.REC.1398.071

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

The expression rate of anti-antimicrobial peptides hBD-2 and LL-37

Timepoint

Before and after 8 weeks of combined training (aerobic + resistance)

Method of measurement

Measurement kits for measuring the hBD-2 and LL-37 variables with methods Real Time-PCR

2

Description

Expression rate of micro-RNAS 155; 326; 23b; 146a; 21

Timepoint

Before and after 8 weeks of combined training (aerobic + resistance)

Method of measurement

Measuring kits for measuring the expression of micro-

RNAS 155; 326; 23b; 146a; 21 by method Real Time -PCR

3

Description

Expression rate of TLR-4; TLR-2

Timepoint

Before and after 8 weeks of combined training (aerobic + resistance)

Method of measurement

Measurement kits for measuring the expression of TLR-4 and TLR-2 with Real Time-PCR method

Secondary outcomes

1

Description

Expanded Disability Status Scale

Timepoint

Before and after 8 weeks of combined training (aerobic + resistance)

Method of measurement

EDSS Test

Intervention groups

1

Description

Intervention group: Exercise training Protocol In this study, 32 training sessions, which included a total of 8 weeks of training and 4 sessions of training each week. 3 sessions will be aerobic training (bicycle and treadmill) and one session of resistance training. Cardio workouts are performed on Saturday, Sunday and Monday, and the Resistance training program is performed on Wednesday every week.

Category

Lifestyle

2

Description

Control group: The group will not receive any exercise activity

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Association of MS patients in Chaharmahal and Bakhtiari province

Full name of responsible person

Saman Yousefi Saqqezi

Street address

5th Street, Moharram 12 St., Basij Sq, Ms Forum.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University

Full name of responsible person

Mohsen Mobini Dehkordi

Street address

ShahrKord University, Rahbar Boulevard, Shahrekord

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8818634141

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mmobinid@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrekord 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

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University

Full name of responsible person

Saman Yousefi Saqqezi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Physiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In this section, part of anthropometric information (height, weight and BMI), and information about the main outcomes of the study are shared after non-identifying people to print to a reputable magazine.

When the data will become available and for how long

Start the access period 3 months after printing results

To whom data/document is available

Only for researchers working in academic and academic institutions.

Under which criteria data/document could be used

1-If needed, and as a non-personally identifiable data, only the journals that the article will be sent to the printing. 2. Physicians in this study

From where data/document is obtainable

Saman Yousefi Saqqezi Email:
samanyousefi25@yahoo.com

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

Confirmation of the relevant advisor and finally approved from vice chancellor for research and technology, University of Shahrekord

Comments