

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the relationship between BDNF, VEGF, proinflammatory and anti-inflammatory cytokines with cognitive function and quality of life following 6 weeks aerobic training in comparison with control group in relapsing-remitting multiple sclerosis patients.

Protocol summary

Study aim

The aim of this clinical trial study is investigating the relationship between cognitive function of the brain and blood samples including VEGF, BDNF, IL6, Tnf-a and IL10 after 6 weeks of aerobic exercise training in Relapsing-Remitting Multiple Sclerosis patients.

Design

In this study, 20 patients with relapsing-remitting MS who have inclusion criteria will refer to Royan Research Institute by a neurologist. The participants then randomly divided into two groups of ten: Intervention of aerobic exercise on a fixed bike and control. For each person, the code is considered to comply with the principles of confidentiality of their data.

Settings and conduct

After the referral of a neurologist, the participant will attend the Royan Research Institute for a study. Pre-post trials include taking blood sample and three cognitive visual tests. Then, intervention group will be asked to enter aerobic training sessions in the exercise room and the control group, without exercise intervention, will be required to take their medication only. All individuals are blind in prior evaluations, that intervention is only a continuation of drug therapy (control), or beside to taking routine medications, they have training intervention (intervention). At the end of 6 weeks, both groups will be asked to return to the institution for final evaluations.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Relapsing-Remitting Multiple Sclerosis patients (RRMS) who will be matched for demographic characteristics (height (160-170 cm), weight (60-70 kg) and body mass index (20-25 kg/m²); educational level (have at minimum; completed the high school diploma); and having normal strength in the lower extremities muscle (Grade 5) taking the drug (Interferon beta-1b

(IFNB)); having their inability score EDSS (Expanded Disability Status Scale) between 2-5 through special neurological assessments; Matching for taking the drug (Interferon beta-1b (IFNB)). Exclusion criteria: Having infectious, metabolic, psychological, cardiovascular and mental disease, having Orthopedic problems in one of the lower extremity joints, a history of blood pressure, smoking or using alcohol

Intervention groups

Intervention group : 6 weeks cycling on a stationary bike for 30 minutes 3 days/week, beside taking routine medications. Control group : taking routine medications

Main outcome variables

Cognitive function of the brain VEGF, BDNF, IL6, Tnf-a and IL10 factors in Blood serum.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090203001637N5**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Sedighe Kahrizi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4511

Email address

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the relationship between BDNF, VEGF, proinflammatory and anti-inflammatory cytokines with cognitive function and quality of life following 6 weeks aerobic training in comparison with control group in relapsing-remitting multiple sclerosis patients.

Public title

Evaluation the relationship between cognitive function and inflammatory factors in patients with MS

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Male and female patients by physicians specializing in neurology examination and diagnosis- relapsing remitting MS Be laid. Age between 18 to 40 years Having Disability 2-5 as base, Expanded Disability Status Scale (EDSS) .

Exclusion criteria:

participating in sports activities in a serious and regular manner at least a year before participating in the study. Having history of cardiovascular disease and blood pressure. Use of steroids drugs. Use of antidepressants drugs. Use of neuroleptics drugs. Use of immunosuppressive drugs. Having history of infectious illness. Having history of metabolic illness. Having history of i mental and cognetive illness. Participants have no desire to continue

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random numbers table.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant are blinded to type of intervention. The people who collect and analysis the blood samples from participants, are blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tarbiat Modares University.

Street address

Medical Ethics Committee, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Al Ahmad Highway, Nasr Bridge

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Tehran

Province

Tehran

Postal code

14115-111

Approval date

2016-10-21, 1395/07/30

Ethics committee reference number

IR.TMU.REC.1395.356

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**

Blood levels of BDNF

Timepoint

Before and after the intervention

Method of measurement

Enzyme -linked immunosorbent assay kits

2

Description

Blood levels of VEGF

Timepoint

Before and after the intervention

Method of measurement

Enzyme -linked immunosorbent assay kits

3

Description

Blood levels of IL6

Timepoint

Before and after the intervention

Method of measurement

Enzyme -linked immunosorbent assay kits

4

Description

Blood levels of IL10

Timepoint

Before and after the intervention

Method of measurement

Enzyme -linked immunosorbent assay kits

5

Description

Brain Cognitive function

Timepoint

Before and after the intervention

Method of measurement

Cognitive Testing Software

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and after the intervention

Method of measurement

Questionare SF 36

Intervention groups

1

Description

Control group:They will take part in pre-post evaluation process only. They have be given medicine and diet similar to intervention group. they will not do and physical training in study period .

Category

N/A

2

Description

Intervention group :6 weeks endurance exercise with stationary bike with 70% maximal heart rate, 3 days in week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neroulogical clinic of Royan research centerr .

Full name of responsible person

Seyyed Masood Nabavi

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Royan Research Center, North Banihashem st, Resalt highway,P.O. Box: 16635-148.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Deen for Research of Faculty of Basic of Medical Science of Tarbiat Modares University (TMU)

Full name of responsible person

Dr. Yaghob Fatolahi

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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

Vice-Deen for Research of Faculty of Basic of Medical Science of Tarbiat Modares University (TMU)

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

Faculty, Tarbiat Modares University, Jalale-Ale Ahmad Highway, P O Box :14115-331.

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Full name of responsible person

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Position

Associate Professor of Tarbiat Modares University,
PhD in physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Full name of responsible person

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Position

Associate Professor of Tarbiat Modares University,
PhD in physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Department of Physical Therapy, Medical Science

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Intervention Program protocol and Statistical Analysis
Plan through publication in dissertation or writing an
article.

**When the data will become available and for how
long**
starting 6 months after publishing of the results.

To whom data/document is available
Research team of this study and other clinical

researchers who are studying for the benefit of these
patients.

Under which criteria data/document could be used
Researchers who intend to write a meta-analysis or
systematic review articles.

From where data/document is obtainable
Dr.Sedighe Kahrizi

**What processes are involved for a request to access
data/document**
It will be approved by the university or the Academic
Institution. .

Comments