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)between2-5 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
kahrizis@modares.ac.ir

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
City
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

Eenzyme -linked immunosorbent assay kits

2

Description
Blood levels ofl VEGF
Timepoint
Before and after the intervention
Method of measurement
Eenzyme -linked immunosorbent assay kits

3

Description
Blood levels of IL6
Timepoint
Before and after the intervention
Method of measurement
Eenzyme -linked immunosorbent assay kits

4

Description
Blood levels of IL10
Timepoint
Before and after the intervention
Method of measurement
Eenzyme -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
Street address
Royan Research Center, North Banihashem st, Resalt highway,P.O. Box: 16635-148.
City
Tehran
Province
Tehran
Postal code
1936773493
Phone
+98 21 2356 2000
Email
massoodnabavi@yahoo.com

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
Street address
Vice-Deen for Research of Faculty of Basic of Medical Science, Tarbiat Modares University,Jalale-Ale Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 2009
Email
fatolahi@modares.ac.ir
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

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University (T.M.U)

Full name of responsible person

Sedighe Kahrizi

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

City

Tehran

Province

Tehran

Postal code

14117113116

Phone

+98 21 8288 4511

Fax

Email

kahrizis@modares.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University (T.M.U)

Full name of responsible person

Dr Sedighe Kahrizi

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

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 4511

Fax

Email

kahrizis@modares.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares Unit (T.M.U)

Full name of responsible person

Dr Sedighe Kahrizi

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

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 4511

Fax

Email

kahrizis@modares.ac.ir

Web page address

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