

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Cardiorespiratory fitness and cardiovascular autonomic control in patients with mild to moderate relapsing remitting Multiple sclerosis following 6 week endurance exercise program

Protocol summary

Summary

In patients with MS, it remains unclear whether exercise improves autonomic control of the heart during exercise is effective or not. While the issue in heart disease, animal studies and human studies in healthy subjects has been proven. Because most MS patients have a rehabilitation program to improve exercise tolerance it should be considered to the effect of this intervention on cardiac autonomic control during exercise. Such a study can also show the causes of intolerance to exercise in MS patients and also effect of exercise on the etiologic factors. Assuming our hypothesis is that the improvement in cardiac autonomic control system with a short-term exercise on MS patients will be seen and associated with improvements in exercise tolerance would be such an increase. The small number of studies and different results prompted us to do this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100524370N1**

Registration date: **2015-11-13, 1394/08/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-13, 1394/08/22

Registrant information

Name

Alireza Aali

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2611 2822

Email address

a-aali@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cardiorespiratory fitness and cardiovascular autonomic control in patients with mild to moderate relapsing remitting Multiple sclerosis following 6 week endurance exercise program

Public title

Exercise effect on patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: definite diagnosis of MS; the MS patients must have passed at least one year of their diagnosis; patients be able to move and walk; age 18-50 years old; all subjects should be sedentary (less than 2 hours of physical activity during a week); they do not have to orthopedic and any chronic illness that not being able to exercise or have an effect on the cardio-

pulmonary system; none of the samples should not take medicines that affect on HR. Exclusion criteria: dementia; alcohol consumption; pregnancy; relapsing MS in a month to study; pacemaker or any disruptions or other serious cardiovascular and respiratory and orthopedic that prevents people from exercising their maximum limit; beta-blockers consumption.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina street, Keshavarz blvd.

City

Tehran

Postal code

Approval date

2015-07-11, 1394/04/20

Ethics committee reference number

ir.tums.rec.1394.362

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating disease of the central nervous system

Primary outcomes

1

Description

Cardiorespiratory fitness and cardiovascular autonomic contro

Timepoint

Before and 6 weeks after intervention

Method of measurement

cardiopulmonary exercise test

Secondary outcomes

1

Description

The effect of aerobic exercise on fatigue variables

Timepoint

Before and 6 weeks after intervention

Method of measurement

Fatigue questionnaire

2

Description

Effects of aerobic training on EDSS variables

Timepoint

Before and 6 weeks after intervention

Method of measurement

Krutze criteria

3

Description

The effect of aerobic exercise on respiratory function such as: Vo₂/HR, O₂ pulse, PETCO₂, PETO₂, Vd/vt, vt, RR, VE, Vco₂ peak RER, VE/CO₂

Timepoint

Before and 6 weeks after intervention

Method of measurement

Cardiopulmonary exercise tes

4

Description

The effect of aerobic exercise on walking capacity variables

Timepoint

Before and 6 weeks after intervention

Method of measurement

Questionnaire about physical activity (IPAQ)

Intervention groups

1

Description

Endurance training intervention for HR - controlled at 50 - 60 rpm is in a lactate threshold. (Equivalent to 70% HR peak or 60% vo₂ peak) on a 6-week cycle is carried out and CPET testing and EKG will be done against the end .

Sessions under supervision, at least 5 times training sessions during two week under the supervision. the subjects must be participate at least 9 Sessions .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr Maryam Abolhasani

Street address

Sina hospital, Imam Khomeini st., Hasan Abad squa.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

Tehran Enghelab Street goce Street Poursina street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Reza Aali

Position

MD, Sports medicine assistant

Other areas of specialty/work

Street address

Imam Khomeini Hospital

City

Tehran

Postal code

Phone

+98 21 2611 2822

Fax

Email

a-aali@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mamryam Abolhasani

Position

Sports medicine specialist

Other areas of specialty/work

Street address

Sina hospital, Imam Khomeini st., Hasan Abad square

City

Tehran

Postal code

Phone

+98 21 6634 8500

Fax

Email

m_abolhasani@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Maryam Abolhasani

Position

Sports medicine specialist

Other areas of specialty/work

Street address

Sina hospital, Imam Khomeini st., Hasan Abad square

City

Tehran

Postal code

Phone

+98 21 6634 8500

Fax

Email

m_abolhasani@sina.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty