Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 programto 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

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Iran (Islamic Republic of)

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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 beable 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/VCO2

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 againat 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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

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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

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

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Position

MD, Sports medicine assistant

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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