Neuroprotective Effects of Exercise in People with Progressive Multiple Sclerosis: a phase II trial

Published: 24-01-2020
Last updated: 19-08-2024

The primary aim of this phase II trial is to assess whether a progressive resistance training program can slow down neurodegeneration in people with PMS. Additional objectives of this study are: 1. To determine the effect of exercise on disability....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON55151

Source
ToetsingOnline

Brief title
Exe*cise PRO-MS

Condition

- Demyelinating disorders

Synonym
Progressive MS, Progressive Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Dutch MS Research Foundation (MS 18-358f)

Intervention

Keyword: Brain Atrophy, Neurodegeneration, Progressive Multiple Sclerosis, Progressive Resistance training

Outcome measures

Primary outcome

The primary outcome measure of this study is neurodegeneration, primarily

operationalized by brain atrophy on brain MRI

Secondary outcome

Secondary outcome parameters will include disability parameters and

cardiovascular risk profile.

Study description

Background summary

To date there are little to no disease modifying treatment options for people with progressive multiple sclerosis (PMS). Neurodegeneration, rather than inflammation, seems to play a key role in the progressive phase of MS. Evidence from animal models and healthy aging individuals suggests that exercise (e.g. resistance training and endurance training) might be a possible therapy affecting neurodegeneration. However, neuroprotective effects of exercise interventions have not been examined yet in PMS and the possible mode of action of these effects needs to be elucidated.

Study objective

The primary aim of this phase II trial is to assess whether a progressive resistance training program can slow down neurodegeneration in people with PMS. Additional objectives of this study are: 1. To determine the effect of exercise on disability. 2. To explore the relationship between disability and neurodegeneration. 3. To determine the effect of exercise on cardiovascular risk profile. 4. To assess the relative responsiveness of different neurodegeneration parameters.

Study design

In a phase II clinical trial with an extended baseline, 30 patients with PMS will be assigned to progressive resistance training (PRT). The duration of the study is 48 weeks, consisting of 16 weeks baseline (no intervention), 16 weeks training and 16 weeks follow-up. Due to the extended baseline design patients are their own control group.

Intervention

participants will be assigned to: 1. A 16-week PRT program, one hour per training, three times per week focusing on large muscle groups, to improve muscle strength.

Study burden and risks

Over a period of 48 weeks there will be eight 3-hour measurement sessions. Blood sampling might be unpleasant and can result in bruising. Physical tests can result in muscle soreness and fatigue for maximally 48 hours. To reduce fall-risk during physical tests an experienced assessor will perform measurements. All measurements have been performed previously in patients with multiple sclerosis and are safe and feasible. The training interventions are time consuming, 3-times per week for sixteen weeks. Exercise programs may result in fatigue and muscle soreness and there are some minor risks of falling and bruising as is common by doing sports

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Progressive Multiple Sclerosis diagnosis defined as: *definite diagnosis of MS according to the 2017 McDonald Criteria with gradual progression of neurological impairments according to the Lublin criteria 2013.*
EDSS Scale 3.5 - 6
Able to participate in the exercise programs, i.e. no contra-indications for training according to the guidelines of the American college of Sports Medicine
- No history of heart problems
- No symptoms that might indicate heart problems
- No other major health issues
Age between 18 and 70 years old
Able to understand therapists instructions
Fulfilling the safety criteria for magnetic resonance assessment
- No metal inside the body
- Not claustrophobic
- No pregnancy

Exclusion criteria

Diagnosed with primary progressive multiple sclerosis
Relapse within 3 months of baseline visit
Severe comorbidity (Cumulative Illness Rating Scale >= 3 on 1 or more organ systems).
Initiation of Fampridine within 6 months of baseline visit.
Depression, Hospital Anxiety and Depression Scale score, depression subscale >=11 (i.e. indicative of clinical anxiety disorder or clinical depression)
Other neurological- and/or musculoskeletal disorders
Already participating in a (guided) high intensity exercise training
Participating in another intervention study
Pregnancy, given birth previous 6 months, or active pregnancy wish

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2020
Enrollment:	59
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29122
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71762.029.19
Other	NL8265