Cardiorespiratory fitness in newly diagnosed patients with Relapsing Remitting Multiple Sclerosis compared to matched healthy controls: already lagging behind from the start?

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This pilot study aims to explore whether and why the cardiorespiratory fitness is compromised in newly diagnosed patients with early Relapsing Remitting Multiple Sclerosis (RRMS) with no or minimal clinical symptoms (i.e. Expanded Disability Status...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON48103

Source
ToetsingOnline

Brief title
VO2max in early MS / LOW2early

Condition

- Demyelinating disorders

Synonym
Multiple Sclerosis (MS)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiorespiratory fitness, Healthy siblings, Multiple Sclerosis, Relapsing Remitting MS

Outcome measures

Primary outcome

Maximal exercise capacity, lung function, and mitochondrial function of

muscles.

Secondary outcome

Blood parameters: Haemoglobin concentration, hematocrit, C-reactive protein

(CRP).

Study description

Background summary

Scientific evidence consistently shows reduced cardiorespiratory fitness in people with Multiple Sclerosis (MS) compared to healthy peers. It is often suggested that this is caused by the fact that MS patients have an inactivity-related physiological profile caused by a more sedentary lifestyle compared to healthy controls. However, in keeping with a recent Norwegian study showing that reduced cardiorespiratory fitness increases the susceptibility to develop MS and clinical observations, it is hypothesized that low cardiorespiratory fitness is already present at the onset of the disease and is thus not the result of neurodegenerative disease course. Cardiorespiratory fitness depends on the functional integration of the cardiovascular, respiratory, and skeletal muscle system. It is therefore important to examine in early MS how each step of the oxygen transport pathway contributes to cardiorespiratory deconditioning, and whether explanatory modifiable determinants of reduced cardiorespiratory fitness can be found.

Study objective

This pilot study aims to explore whether and why the cardiorespiratory fitness is compromised in newly diagnosed patients with early Relapsing Remitting Multiple Sclerosis (RRMS) with no or minimal clinical symptoms (i.e. Expanded Disability Status Scale (EDSS) score 0-2 and normal pyramidal and cerebellar functions) compared to matched healthy siblings or other matched healthy controls.

Study design

Observational case-control study with a cross-sectional design

Study burden and risks

There will be one enrolment consultation of 1 hour. After inclusion, the measurements (2 times in 2 weeks) will take approximately 2 hours each to complete. The risks and burden will be related to the testing procedures, i.e. cardiopulmonary exercise testing, lung function examination, muscle biopsy, and blood sampling. It should be noted that all these are common clinical diagnostic procedures, and proven to be safe (in patients with MS). There is no direct benefit of study participation. Participants will, however, contribute to increasing knowledge and insight of exercise tolerance in patients with early MS. The risk-classification for this non-intervention study is *negligible*.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

MS patients
In order to be eligible to participate in this study, the MS patients must meet all of the following criteria:
- definite diagnosis of Relapsing Remitting MS according to the most recent international diagnostic criteria;
- diagnosis within 12 months prior to inclusion date;
- disease severity: EDSS score of maximal 2 with normal pyramidal and cerebellar functions (i.e. Functional Systems Score for pyramidal functions = 0 and Functional Systems Score for cerebellar functions = 0).
- age at definite diagnosis between 18-65 years.

Healthy Siblings/Controls (controls)
In order to be eligible to participate in this study, the healthy controls must meet the following criteria:
- healthy sibling of participant with MS, and matching with respect to sex, age (± 5 years), level of physical activity in the past year;
- healthy persons, matching to MS participants with respect to sex, age (± 5 years), and level of physical activity in the past year.
- age between 18-65 years

Exclusion criteria

- Physician-confirmed diagnosis of (other) neurological disorders or systemic or malignant neoplastic diseases.
- Serious comorbidities precluding Cardiopulmonary Exercise test (CPET) or Lung function examination.
- Use of heart rate regulating medication (e.g. Beta-blockers).
- Use of medication for lung diseases.
- Being pregnant, or receiving medical help/fertility treatment to become pregnant.
- Body Mass Index of 30 or higher.
- Sports and exercise activities in the past year of > 10 hours/week.

- Does not speak Dutch.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-10-2019
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	12-02-2019
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL67705.029.18