COVID-19 and SARS-CoV-2 antibodies in multiple sclerosis patients: a large study in the Amsterdam MS Cohort

Published: 28-07-2020
Last updated: 09-04-2024

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

Summary

ID

NL-OMON49502

Source
ToetsingOnline

Brief title
COMS-19

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Stichting MS Research

Intervention

Keyword: COVID-19, Multiple sclerosis

Outcome measures

Primary outcome

Association of the course of COVID-19 and immunomodulatory treatment.

Secondary outcome

- establishing the percentage of MS patients who have currently developed SARS-CoV-2 antibodies in the Netherlands.

- In the antibody positive patients we will associate disease course (asymptomatic, mild symptoms, severe symptoms, hospitalization) with MS characteristics, demographics and comorbidity.

- Characteristics of patients with SARS-CoV-2 antibodies versus patients without antibodies in regards to demographics, MS characteristics, immunomodulatory treatments, prior medical history and degree of social isolation

- With the Sanquin antibody test, we will study the antibody profile (IgM/G/A, IgG1/3) and repertoire (anti-SP, anti-NP).

Study description

Background summary

The course of COVID-19 in MS patients is still unclear. Patients with MS are possibly more or less vulnerable to infection with SARS-CoV-2.
Furthermore the use of immunomodulatory treatment and/or MS characteristics

could have an effect on the course of COVID-19 disease.

Study objective

The objectives of this study are 1. to study the course of COVID-19 in MS patients in relation to immunomodulatory treatment and other patient and MS characteristics to study the proportion of MS patients with SARS-CoV-2 antibodies and 2. to study the proportion of MS patients with SARS-CoV-2 antibodies to study the course of COVID-19 in MS patients in relation to immunomodulatory treatment and other patient and MS characteristics and 3. to establish the antibody profile in positive tested patients and 4. to study the longitudinal course of these antibody profiles in positive tested patients.

Study design

Phase I is cross sectional with blood testing of antibodies and a questionnaire. Phase II includes only patients who tested positive in phase one and will be a longitudinal follow-up at 6 and 12 months with blood testing and a questionnaire at both time points.

Study burden and risks

All subjects will be asked to complete the online questionnaire one to three times (approximately 10 minutes) containing questions regarding COVID-19 complaints, medical history and MS characteristics. In addition, blood will be drawn at VUmc laboratory one to three times.

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

Under current follow-up in the MS Center Amsterdam
Current diagnosis of multiple sclerosis
18 years or older

Exclusion criteria

No informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-08-2022

Enrollment:	750
Type:	Actual

Ethics review

Approved WMO Date:	28-07-2020
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	NL74243.029.20