COVID-19 in patients with chronic inflammatory diseases: a prospective cohort study

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The primary objective will focus on both the difference in incidence and disease severity of COVID-19 between patients with a chronic inflammatory disease and the control group.

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

Summary

ID

NL-OMON54401

Source
ToetsingOnline

Brief title
COVID-19 in patients with chronic inflammatory diseases

Condition

- Autoimmune disorders
- Viral infectious disorders

Synonym
coronavirus, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: Reade Research BV

Intervention

Keyword: Chronic inflammatory diseases, Corona virus, COVID-19, Immunosuppressive medication

Outcome measures

Primary outcome

The primary objective will be to compare the disease severity of COVID-19 between patients with a chronic inflammatory and a control population. Disease severity is defined as the (unplanned) hospital admission rate of participants that are both IgM- or IgG-SARS-CoV-2 antibody positive and symptomatic. Symptomatic is defined as symptoms or signs of nasopharyngitis, cough, dyspnea, fever, or any other symptom or sign that may be associated with a viral infection, as assessed by the patient. Unplanned refers to the fact that elective hospital admissions (e.g., for planned surgery) are excluded.

Secondary outcome

One of the secondary objectives is to study the following differences between patients and controls, and subsequently, within the inflammatory disease group, between conventional DMARDs (including glucocorticoid) users and biologics users, in:

- Cumulative (6-month) incidence of IgM or IgG antibodies against SARS-CoV-2;
- Disease severity of hospitalized COVID-19 patients (defined as ICU admission or death);
- Antibody profile (IgM/G/A, IgG1/3) and repertoire (anti-SP, anti-NP), and IgG antibody avidity.

We will also investigate whether physicians and/or patients decide to adjust the use or dose of immunosuppressive medication due to the SARS-CoV-2 pandemic, and how these potential adjustments influence disease activity.

An addendum has been added to the protocol with additional secundary endpoints for the SLE population. In this population, the role of PI3 kinase (PI3K) signalling will be investigated. Also, we will evaluate whether an increased expression of type I interferon regulated genes is associated with the reaction to COVID-19.

Study description

Background summary

In December 2019 the first case of COVID-19 was identified in China. In the months thereafter the number of laboratory confirmed cases exponentially increased around the world. The World Health Organization has officially declared the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) a public health emergency of international concern and more recently a pandemic. Although some studies focused on identifying the risk factors for disease severity, none of these studies have investigated the use of immunosuppressive medication and its influence on disease severity and antibody response.

A large proportion of patients with a chronic inflammatory disease are being treated with immunosuppressive medication. In previous studies immunosuppressive medication have been associated with an increased risk for serious infections. However, none of the previous research has specifically focused on the influence of immunosuppressive medication on viral infections in terms of disease severity or antibody response. With the emergence of the SARS-CoV-2 there is the unique opportunity to study these questions. This group of patients is extra interesting since a proportion of patients with rheumatic diseases is treated with hydroxychloroquine and tocilizumab. Recent studies indicate that tocilizumab reduces the likelihood of progression to mechanical ventilation or death in hospitalized patients with COVID-19. For hydroxychloroquine, which has recently been identified to have in vitro antiviral properties, no protective effects have been demonstrated. However,

studies investigating prophylactic effects of tocilizumab and hydroxychloroquine have not yet been performed. It would therefore be interesting to study disease severity and the antibody response in this specific category of patients.

In addition, multiple variants of SARS-CoV-2 with varying pathogenicity and transmissibility have circulated through society. It is expected that SARS-CoV-2 will continue to evolve into new variants and impact society, possibly causing endemics. The vast majority of people, including patients with chronic inflammatory diseases, have developed immunity against SARS-CoV-2, either via vaccination, infection or both. However, data on long-term protection against SARS-CoV-2 in patients with chronic inflammatory diseases are still lacking, which emphasizes the importance of studies with longer follow-up.

Lastly, recent studies have shown that SARS-CoV-2 infections can cause longstanding symptoms that have a negative impact on daily functioning and quality of life, even when the disease course was mild. This phenomenon is called post-COVID syndrome or long COVID. However, data on the prevalence, disease course and impact of long COVID on patients with chronic inflammatory diseases are still scarce. Studies with longer follow-up are necessary to investigate this, which can help in providing information to and improve guidance of patients with chronic inflammatory diseases.

Study objective

The primary objective will focus on both the difference in incidence and disease severity of COVID-19 between patients with a chronic inflammatory disease and the control group.

Study design

This is a prospective observational cohort study with a follow-up of 18 months. The baseline measurement will consist of a digital survey covering demographic variables, specific health-related topics, and COVID-19 relevant questions. Subjects will be asked to fill in the same survey after 1-3, 4-6, 7-9, 10-12, 13-15 and 16-18 months of follow-up, and 2-4 times per year during the next 5 years of follow-up. In addition, during follow-up blood will be drawn up to fourteen times within approximately one week of completion of an online survey. Patients with a chronic inflammatory disease will be asked, but not obliged, to complete additional questionnaires regarding disease activity and to draw additional blood in case of a flare.

Study burden and risks

Risks associated with participation in this study are very low. The research

burden consists of the following: all subjects will be asked to complete the online survey 17-27 times. This survey covers several subjects, among which respiratory illnesses (including hospital and or ICU admittance), rheumatic disease activity and medication use. Demographic data will also be collected at baseline. In addition, blood will be drawn after 1-3, 4-6, 7-14 and 16-18 months of follow up, and up to twice per year during the next 5 years of follow-up. Patients with a chronic inflammatory disease will be asked, but not obliged, to complete additional questionnaires regarding disease activity and to draw additional blood in case of a flare.

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

For patients:

- Older than 18;
- Diagnosed by their treating physician with a inflammatory chronic disease.

For controls:
- Family or close friend of an eligible patient (preferably of the same gender).

Exclusion criteria

- Language problems precluding the completion of the questionnaire;
- Likelihood of absence in the next 6 months;
- Lack of informed consent.

For controls:
- Age difference with matched patient > 5 years.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-04-2020
Enrollment:	8000
Type:	Actual

Ethics review

Approved WMO

Date:	06-04-2020

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL73521.029.20
Other	NL8513