COVID-19 in rheumatic patients: a prospective cohort study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26858

Source
Nationaal Trial Register

Brief title
TBA

Health condition

All systemic autoimmune diseases

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Our primary study parameter is the percentage of participants with a positive IgM or IgG response admitted to the hospital.

Secondary outcome

Other parameters include:
- The percentage of participants with a positive IgM or IgG response admitted to the ICU, and mortality due to SARS-CoV-2;
- The geometric mean antibody titre over time;
- The geometric mean and incidence of different antibody profiles (IgM/G/A, IgG1/3) and repertoire (anti-SP, anti-NP);
- The geometric mean antibody avidity;
- The percentage of patients who changed the dosage or use of their DMARD;
- Mean rheumatic disease activity.

Study description

Background summary

The influence of the presence of an inflammatory rheumatic disease and its treatment on the severity of and immune response towards (viral) infections is not clear. The emergence and pandemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) provides the opportunity to assess these influences on the incidence of COVID-19, its clinical severity, and the antibody response in patients with a rheumatic disease compared to a control population.

The primary objective of this study is to compare the disease severity of COVID-19 between patients with a rheumatic disease 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 means that elective hospital admissions (e.g., for planned surgery) are excluded.

The secondary objectives include studying the following differences between the groups, and subsequently, within the inflammatory disease group, between conventional disease-modifying anti-rheumatic drug (DMARD, including glucocorticoid) users and biologics users in:
1. Cumulative (6-month) incidence of IgM or IgG antibodies against SARS-CoV-2;
2. Disease severity of hospitalized COVID-19 patients (defined as ICU admission or death);
3. Antibody profile (IgM/G/A, IgG1/3) and repertoire (anti-SP, anti-NP), and IgG antibody avidity.

We will also investigate what people do with regards to use and dosage of DMARDs during the SARS-CoV-2 pandemic. Finally, we will investigate whether potential changes in DMARD use and dosage influence the disease activity.

This is a prospective observational cohort study with a follow-up of 6 months. The first visit will consist of an online survey. This survey will also be completed after 3 and 6 months of follow-up. Two blood tests will also be performed between 1-2 and 4-6 months of follow-up.

The study population will consist of participants with an inflammatory rheumatic disease (i.e.

rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis). These patients will be recruited at the three sites of the Amsterdam Rheumatology & immunology Center, which are Reade and the Amsterdam UMC location VUmc and AMC. Furthermore, each patient will be asked to provide a healthy control without a rheumatic disease (and DMARD use) from their social group or household. These two subjects will have a comparable chance of exposure to SARS-CoV-2. All participants need to be at least 18 years old. We expect to include 4000 patients and 4000 controls.

Study objective

Our hypothesis is that more hospital admissions will be reported in patients with a rheumatic disease compared to the control population.

Study design

Survey: 0, 3, and 6 months; Blood sample: 1-2 and 4-6 months after the baseline survey

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age ≥ 18 years.

For patients:
- Diagnosed by their treating physician with a systemic autoimmune disease.

For controls:
- Belonging to family or close friend of patient (of the same gender).

Exclusion criteria

Patients who meet the following criteria will be excluded from the study:
- Language problems precluding the completion of the questionnaire;
- Likelihood of absence in the next 6 months;
- Lack of informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-04-2020
Enrollment:	8000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-04-2020
Application type:	First submission

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
NTR-new	NL8513
Other	METC VUmc : 2020.169 - NL73521.029.20

Study results