COVID-19 in rheumatic patients: a prospective cohort study

Gepubliceerd: 07-04-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26858

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

All systemic autoimmune diseases

Ondersteuning

Primaire sponsor: Reade Research BV
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Our hypothesis is that more hospital admissions will be reported in patients with a rheumatic

disease compared to the control population.

Onderzoeksopzet

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

Contactpersonen

Publiek

Reade, Jan van Breemen Research Institute
Femke Hooijberg

0202421633

Wetenschappelijk

Reade, Jan van Breemen Research Institute
Femke Hooijberg

0202421633

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-04-2020
Aantal proefpersonen:	8000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8513
Ander register	METC VUmc : 2020.169 - NL73521.029.20

Resultaten