

# The early stage SARS-CoV-2 immune response including antibody kinetics in out of hospital patients with mild COVID-19 symptoms

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To describe the early stage SARS-CoV-2 immune response including antibody kinetics in patients with mild COVID-19 symptoms who were not admitted to the hospital.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON50008

### Source

ToetsingOnline

### Brief title

Early stage immune responses against SARS-CoV-2

### Condition

- Viral infectious disorders

### Synonym

coronavirus, COVID-19

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Reade, reumatologie en revalidatie te Amsterdam

**Source(s) of monetary or material Support:** Dit zal nog nader bepaald worden

## Intervention

**Keyword:** Antibodies, Immunity, SARS-CoV-2

## Outcome measures

### Primary outcome

The geometric mean titres of total and isotype-specific (including IgM, IgG) antibodies in patients with mild COVID-19 symptoms which did not require hospital admittance.

### Secondary outcome

none.

## Study description

### Background summary

A large part of the population will eventually experience the coronavirus. Majority of these people will hardly experience any complaints. It is important to investigate how our immune system responds to getting COVID-19 and preferably to determine this as early as possible. In particular, by looking at this early stage.

### Study objective

To describe the early stage SARS-CoV-2 immune response including antibody kinetics in patients with mild COVID-19 symptoms who were not admitted to the hospital.

### Study design

A prospective cohort study will be conducted at the Amsterdam Rheumatology & immunology Center, location Reade. The follow-up duration for participants will be 6 months. After a baseline visit, additional visits are planned between 3-5 days, between 6-7 days, 11-12 days, 1 month and at 3 and 6 months. At each visit blood will be drawn. The study is expected to cover 10 months for recruitment, follow-up and analysis

## Study burden and risks

This study is relevant for clinical practice, especially since the COVID-19 pandemic provides a unique opportunity to provide insight in the early antibody/immune response in patients with mild COVID-19 symptoms who do not require hospital admittance and aid in assessing the performance of the assay in this patient category. Approaching healthy volunteers during the early stage of COVID-19 infection is therefore essential since most sero-surveillance studies will be performed in a similar population. This study will therefore be highly relevant.

Disadvantages for participants will be that blood withdrawal will take place 7 times during the study. The risk of drawing blood is negligible.

## Contacts

### Public

Reade, reumatologie en revalidatie te Amsterdam

Dr. Jan van Bremenstraat 2  
Amsterdam 1056 AB  
NL

### Scientific

Reade, reumatologie en revalidatie te Amsterdam

Dr. Jan van Bremenstraat 2  
Amsterdam 1056 AB  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

## Inclusion criteria

1. Age > 18 years;
2. Symptoms associated with a COVID-19 infection;
3. Travelled to an endemic region or have contact with a person who is suspected for/or diagnosed with a COVID-19 infection or had a SARS-CoV-2 positive PCR;
4. Mild COVID-19 symptoms which did not require hospital admittance;
5. No more than 10 days between symptoms associated with a COVID-19 infection and the screening visit.

## Exclusion criteria

1. Language problems precluding the completion of the questionnaire or understanding the informed consent;
2. Likelihood of absence in the next 4 weeks.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 15-05-2020

Enrollment: 14

Type: Anticipated

## Ethics review

Approved WMO

Date: 26-05-2020  
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	NL73926.029.20