

# SARS-CoV-2 serology testing in healthcare professionals

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

## Summary

### ID

NL-OMON50162

### Source

ToetsingOnline

### Brief title

SARS-CoV-2 serology testing in healthcare professionals

### 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 onderzoek zal gefinancierd worden door Reade

## Intervention

**Keyword:** healthcare, professionals, SARS-CoV-2, serology

## Outcome measures

### Primary outcome

The primary study parameter is the proportion of Reade employees which is SARS-CoV-2 IgM or IgG positive at baseline and after 6 months of follow-up.

### Secondary outcome

The secondary study parameter is the proportion of asymptomatic SARS-CoV-2 positive healthcare professionals.

## Study description

### Background summary

COVID-19 has caused an extensive burden on the healthcare system. The main reasons for this burden is the sudden increased influx of COVID-19 patients, outage of healthcare professionals and third probably unnecessary self-isolation of healthcare professionals. To keep the health institutions and services up and running we need to better understand the in-hospital transmission. One way to do that is to start testing healthcare professionals, preferable in a more sustainable way by serology testing, on their presence of SARS-CoV-2 IgM or IgG antibodies.

### Study objective

The aim of this study is to establish how many employees at Reade have had an infection with SARS-CoV-2, tested with a novel assay for the detection of antibodies against SARS-CoV-2 developed by Sanquin. This study will focus on our own institute, Reade, which is a rheumatology and revalidation centre in Amsterdam.

### Study design

The design of the study is an explorative descriptive study. At two time points participants are asked to fill out a short questionnaire. Next to that they are also asked to donate blood at those two time points.

The study is expected to cover approximately 9 months; recruitment and enrolment will comprise 1 month, follow-up 6 months and analyses 2 months.

### **Study burden and risks**

This is an observational study. The study comprises a questionnaire that does not probe any \*sensitive\* topics. The blood test does not probe any sensitive determinants. During each visit 10 cc blood will be drawn. As such, we have asked the METC for exemption for insurance which covers compensation for injury.

## **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

- \* Employed at Reade;
- \* Age \* 18 years.

## Exclusion criteria

- \* Language problems precluding the completion of the questionnaire;
- \* Lack of informed consent.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 30-07-2020

Enrollment: 700

Type: Actual

## Ethics review

Approved WMO

Date: 07-07-2020

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	NL74098.029.20