

# Mucosal immunity in patients diagnosed with SARS-CoV-2 infection and their household contacts

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The aim of this study is to collect nasal fluid (mucosal lining fluid) from patients with a confirmed SARS-CoV-2 infection who remain in home isolation, as well as from their household contacts who remain in home quarantine. We aim to measure...

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

## Summary

### ID

NL-OMON49964

### Source

ToetsingOnline

### Brief title

Mucosal immunity against coronavirus infection

### Condition

- Viral infectious disorders

### Synonym

coronavirus, COVID-19

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Antibodies, Household contacts, Mucosal immunity, SARS-CoV-2

## Outcome measures

### Primary outcome

This is an exploratory study in which the primary aim is to study the development of antibodies to SARS-CoV-2 in nasal fluid of COVID-19 patients and their household contacts.

Primary outcome:

- Descriptive analysis of SARS-CoV-2 IgG and IgGA concentrations in nasal fluid at the various time points.

### Secondary outcome

- Detection of SARS-CoV-2 in diagnostic specimen
- Descriptive analysis of inflammatory markers in nasal fluid
- Descriptive analysis of correlation of antibodies with viral diagnostics and disease symptoms

## Study description

### Background summary

COVID-19 is caused by the new coronavirus SARS-CoV-2. The WHO has recently declared the SARS-CoV-2 outbreak a pandemic, and it has already sparked major disruptions in daily life, including in the Netherlands.

The majority of COVID-19 patients has fever and respiratory complaints. In the Netherlands, patients with a suspicion of COVID-19 need to be notified to the GGD. To prevent further spread, patients will remain in home quarantine, awaiting diagnostic testing. The GGD will then organize a home visit for

collection of a diagnostic specimen. Following a positive diagnostic test, patients will remain in home isolation, if the home situation permits. High-risk contacts including household contacts will be actively monitored by the GGD and are not allowed to go to school or work for 14 days (home quarantine). Household contacts are currently not tested anymore due to limited diagnostic capacity. Because household contacts of a confirmed case already remain in home quarantine and there are not yet effective interventions available, additional diagnostic testing does not influence clinical decision making.

At the moment there is no knowledge about the immunological response to SARS-CoV-2 infection. It remains unknown whether (sub)clinical infection with SARS-CoV-2 results in a mucosal immune response. An important question is whether subclinical infections, particularly in children, contribute to the spread of coronavirus.

### **Study objective**

The aim of this study is to collect nasal fluid (mucosal lining fluid) from patients with a confirmed SARS-CoV-2 infection who remain in home isolation, as well as from their household contacts who remain in home quarantine. We aim to measure antibodies and other immunological biomarkers against SARS-CoV-2 in collected samples.

### **Study design**

This is a monocenter, prospective observational cohort study with non-invasive procedures.

### **Study burden and risks**

The collection of nasal fluid can cause sneezing and watery eyes. This is of a temporary nature and there are no major risks associated with participation. We have reduced the number of collection time points as much as possible.

## **Contacts**

### **Public**

Radboud Universitair Medisch Centrum

Geert Grooteplein 10

Nijmegen 6500HB

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### **Scientific**

Radboud Universitair Medisch Centrum

Geert Grooteplein 10  
Nijmegen 6500HB  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

### Inclusion criteria

Patient with a laboratory-confirmed SARS-CoV-2 infection in home isolation with at least two household contacts remaining in home quarantine at the same address.

### Exclusion criteria

Patients with a negative indication for home isolation

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2020
Enrollment:	200
Type:	Actual

## Ethics review

Approved WMO	
Date:	18-03-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	23-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	25-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	14-04-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	15-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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**

CCMO

### **ID**

NL73418.091.20