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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	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 suspician 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

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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	ID
CCMO	NL73418.091.20