Mucosal and circulating immunity against SARS-CoV-2 among healthcare professionals working with COVID-19 patients

Published: 27-07-2020
Last updated: 09-04-2024

To investigate the prevalence and evolution of mucosal IgA and circulating IgA and IgG SARS-CoV-2 antibody titers and their relation to symptom severity and the presence of PCR-detectable (other) coronaviruses.

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

Summary

ID

NL-OMON49305

Source
ToetsingOnline

Brief title
Immunity screening COVID-19

Condition

- Viral infectious disorders

Synonym
COVID-19, SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: Circulating immunity, COVID-19, Mucosal immunity, SARS-CoV-2

Outcome measures

Primary outcome

The main study outcome will be the prevalence of mucosal IgA and circulating IgA and IgG SARS-CoV-2 antibodies.

Secondary outcome

Secondary study outcomes will be the evolution of the titers of these mucosal IgA and circulating IgA and IgG SARS-CoV-2 antibodies over time and the relation of their presence to symptom severity. Furthermore, the potential relation between the presence of mucosal IgA SARS-CoV-2 antibodies and the presence of PCR-detectable coronaviruses other than SARS-CoV-2 in saliva will be assessed.

Study description

Background summary

Because of the current SARS-CoV-2 pandemic, in absence of a vaccine, it is of great importance to know to what extent herd immunity forms in order to decide on *social distancing* policies. In a recent informal, voluntary immunity screening among 130 healthcare professionals, 70% of the people with circulating antibodies were found to have isolated SARS-CoV-2 IgA in their blood. This might indicate the role of the mucosal immunity in the defence against SARS-CoV-2.

Study objective

To investigate the prevalence and evolution of mucosal IgA and circulating IgA and IgG SARS-CoV-2 antibody titers and their relation to symptom severity and

the presence of PCR-detectable (other) coronaviruses.

Study design

The study design is an observational study, namely a prospective cohort study.

Study burden and risks

Blood and saliva will be sampled at 3-month intervals for immunological testing for a total study duration of 24 months. Only if circulating SARS-CoV-2 IgA and/or IgG antibodies are found, participants will receive a questionnaire. The risks and burden associated with these study visits are considered to be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthcare professionals working or having worked (in a department) with COVID-19 patients within the LUMC

Exclusion criteria

below 18 years old

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2020
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	27-07-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	09-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL74102.058.20