

# Sero-surveillance SARS-CoV-2

No registrations found.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Positive opinion           |
| <b>Status</b>                | Recruiting                 |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON26401

### Source

Nationaal Trial Register

### Brief title

S3-study

### Health condition

COVID-19, humane coronaviruses NL63, 229E, OC43, HKU1

## Sponsors and support

**Primary sponsor:** Amsterdam UMC

**Source(s) of monetary or material Support:** Amsterdam UMC Corona Research Fund

## Intervention

## Outcome measures

### Primary outcome

prevalence and time to SARS-CoV-2 seroconversion (IgG and/or IgM) compared between groups. We will test for differences between groups (dichotomous & survival data), assuming a 10% minimally relevant difference. If groups are not statistically different we will use non-inferiority analysis methods to test whether the difference between groups is within the non-inferiority margin of 10%.

### Secondary outcome

presence of non-SARS-CoV-2 coronavirus antibodies and its association with SARS-CoV-2 seroconversion and disease severity. Influence of self-reported exposure to COVID-19 patients as a continuous determinant on SARS-CoV-2 seroconversion.

## Study description

### Background summary

Prospective cohort study using serial testing for SARS-CoV-2 antibodies in hospital personnel. Inclusion was stratified into three groups: an exposed (personnel working with COVID-19 patients), intermediate (personnel working with non-COVID-19 patients), and control group (personnel not working in patient care). Serology tests were accompanied with digital surveys on COVID-19 like complaints and exposure to COVID-19 patients during and outside of work activities. By comparing seroconversion percentages between groups we will be able to elucidate whether hospital personnel caring for patients have an increased risk on contracting COVID-19 compared to the control group. The addition of the intermediate group will differentiate whether this increased risk is caused by caring for COVID-19 patients or through spread among personnel, e.g. due to lack of social distancing when working in patient care. Furthermore, we will test for the presence of non-SARS-CoV-2 coronavirus-antibodies in our cohort and whether this is associated with SARS-CoV-2 seroconversion and COVID-19 disease severity.

### Study objective

1. Hospital personnel working in patient care have a higher chance of contracting COVID-19 due to their contact with COVID-19 patients. Alternatively, 2. Hospital personnel working in patient care have a higher chance of contracting COVID-19 due to a lack of social distancing during their work.

### Study design

Measurements will take place every 4 weeks for a total number of at least 4 times (except for the intermediate group which is only measured once, during measurement moment 4). Depending on the development of the pandemic (e.g. second and subsequent waves) additional measurements will be planned.

### Intervention

none

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

Exposed group: nurses & physicians caring for suspected or confirmed current COVID-19 patients on a COVID-19 unit, ICU or emergency ward.

Intermediate group: nurses & physicians caring for patients without suspected or confirmed current COVID-19 (in contrast to the other groups, this group is only measured once)

Control group: hospital personnel not working in patient care

### Exclusion criteria

Age <18 years old.

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| Study type:         | Observational non invasive      |
| Intervention model: | Parallel                        |
| Allocation:         | Non-randomized controlled trial |
| Masking:            | Open (masking not used)         |
| Control:            | N/A , unknown                   |

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 23-03-2020  
Enrollment: 800  
Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion  
Date: 19-05-2020  
Application type: First submission

## 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                   |
|----------|----------------------|
| NTR-new  | NL8645               |
| Other    | METC VUmc : 2020.154 |

## Study results