Control of COVID-19 in hospitals (COCON-study)
Sero-epidemiology in healthcare workers

Published: 30-04-2020
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Primary objective* To determine the seroprevalence of SARS-CoV-2 neutralising antibodies in HCWs in Dutch hospitals.Secondary objectivesBaseline, all participants * To determine the seroprevalence of SARS-CoV-2 total antibodies in HCWs in Dutch...

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

Summary

ID

NL-OMON49380

Source
ToetsingOnline

Brief title
COCON study

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
COVID-19, new coronavirus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: COVID-19 SARS-CoV-2, healthcare workers, Sero-epidemiology

Outcome measures

Primary outcome

Main study endpoint

* Seroprevalence of SARS-CoV-2 neutralising antibodies.

Secondary outcome

Secondary study endpoints

* Seroprevalence of SARS-CoV-2 total antibodies.

* SARS-CoV-2 serum neutralisation titer (serum).

* SARS-CoV-2 sqRT-PCR cycling threshold (Ct) value (nasopharyngeal/throat swab).

* Median tissue culture infectious dose (TCID50) (nasopharyngeal/throat swab).

* Cumulative incidence of seroconversion for SARS-CoV-2 (neutralising)

antibodies.

* Cumulative incidence of sqRT-PCR- and/or virus culture-confirmed SARS-CoV-2

(re)infection.

* Cumulative incidence of self-reported symptoms suspected for COVID-19.

* Duration (number of days) of self-reported symptoms suspected for COVID-19.

* Duration (number of days) of (unplanned) absenteeism.

* Duration (number of days) of (unplanned) absenteeism because of documented

SARS-CoV-2 infection.

* Duration (number of days) of (unplanned) absenteeism because of self-reported

symptoms suspected for COVID-19.

* Duration (number of days) of (unplanned) absenteeism because of imposed

quarantine for being exposed to SARS-CoV-2 infection.

* Cumulative incidence of hospital admission for any reason.

* Cumulative incidence of hospital admission for documented SARS-CoV-2

infection.

* Duration (number of days) of hospital admission for any reason.

* Duration (number of days) of hospital admission for documented SARS-CoV-2

infection.

* Cumulative incidence of all-cause death.

* Cumulative incidence of death due to documented SARS-CoV-2 infection.

Study description

Background summary

Since December 2019, the world has been in the grip of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease it causes, coronavirus disease 2019 (COVID-19). Effective management of this pandemic requires estimation of the burden of disease. Currently available literature on COVID-19 mostly represents severe cases admitted to the hospital; data on mild and unsuspected clinical presentations and asymptomatic infections are largely unknown. Sero-epidemiologic studies are urgently needed to help uncover the burden of disease, in particular the rate of asymptomatic infections, and to get better estimates on the incidence of disease. Sero-epidemiologic studies can help identify the extent to which the virus has spread and whether this has led to protective immunity. Such information could help guide infection control policies. This study will evaluate the sero-epidemiology of SARS-CoV-2 in healthcare workers (HCWs) in Dutch hospitals.

Study objective

Primary objective
* To determine the seroprevalence of SARS-CoV-2 neutralising antibodies in HCWs in Dutch hospitals.

Secondary objectives
Baseline, all participants

* To determine the seroprevalence of SARS-CoV-2 total antibodies in HCWs in Dutch hospitals in areas with varying incidence of COVID-19 upon enrolment (baseline).
* To determine if the seroprevalence of SARS-CoV-2 (neutralising) antibodies in HCWs is related to illness or (unplanned) absenteeism in the four months before enrolment.
* To determine if the seroprevalence is related to the risk of SARS-CoV-2 exposure
* To describe the clinical presentation of documented SARS-CoV-2 infection in the four months before enrolment.

Study design

This observational study is designed as a cross-sectional study with prospective follow-up in HCWs of ten to twelve Dutch university and non-university hospitals with a representative participation of hospitals from areas with a high incidence of COVID-19 . The duration of follow-up will be three months after enrolment. Follow-up of symptoms that started within these three months will be followed-up until symptom resolution. The study will end after the last follow-up period has ended for the last subject.

Study burden and risks

Participation in this observational study poses a negligible risk and the burden is considered minimal. Subjects will have a 10-mL blood sample drawn on two occasions if no self-reported symptoms suspected for COVID-19. In case of self-reported symptoms suspected for COVID-19 during the follow-up, a 10-mL blood sample and a nasopharyngeal/throat swab will be obtained on three additional occasions. A retrospective questionnaire will be administered at enrolment and 12 weekly short questionnaires during follow-up. In case of self-reported symptoms suspected for COVID-19, a diary on symptoms will be kept until the resolution of symptoms. Participation in the study will not interfere with, or influence local infection control policies for HCWs. There is no direct benefit to subjects, except that individual test results will be made available to the subject during and after the end of the study.

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

A subject who meets all of the following criteria will be eligible to participate in this study:
* HCW employed in one of the participating hospitals

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Age below 18 years
* Direct involvement in the design or execution of this study
* Expected absence from work for more than four weeks during follow-up
* Legally incapacitated or unwilling to provide informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2020
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	30-04-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-05-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-05-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-06-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	23-12-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL73836.041.20
Other	NTR:NL 8528

Study results

Date completed:	10-11-2020
Actual enrolment:	2336