Validation of the RIVM COVID-19 criteria within 'De Corona Check' app using SARS-CoV-2 serology

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The primary objective of this study is to validate the current COVID-19 criteria (for non-vulnerable and vulnerable populations) with data obtained by 'De Corona Check' app and a novel SARS-CoV-2 assay (developed by Sanquin). The secondary...

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

Summary

ID

NL-OMON49450

Source
ToetsingOnline

Brief title
Validation of the current COVID-19 criteria using SARS-CoV-2 serology

Condition

- Viral infectious disorders

Synonym
coronavirus, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: het OLVG

Intervention

Keyword: COVID-19, OLVG Corona Check app, SARS-CoV-2, Serology

Outcome measures

Primary outcome

The main study endpoints are the sensitivity and specificity of the current COVID-19 RIVM guidelines to distinguish between SARS-CoV-2 IgM or IgG antibody positive subjects, as measured by the newly developed assay of Sanquin. In addition, modelling will be used to create a receiver-operator curve of individual symptoms and signs, that may result in criteria with better test characteristics, or alternative criteria that may be used in different populations.

Participants will be divided in non-vulnerable and vulnerable participants. Participants are deemed vulnerable if: they are 70 years of age or older, use immunosuppressive medication, or if they have been diagnosed with a) chronic lung problems, b) heart disease, c) diabetes, OR d) an immune disorder. Non-vulnerable participants meet the COVID-19 criteria if their temperature is above 37.9 degrees and if their cough score is above 3 (out of 10 on the numeric cough scale) and/or their shortness of breath score is above 5 (out of 10 on the numeric dyspnea scale). For vulnerable participants a more strict temperature cut-off of > 37.4 is applied. In these two groups the true incidence of COVID-19 as measured by SARS-CoV-2 IgM or IgG positivity will be compared to the number of subjects fulfilling the current COVID-19 criteria as

defined by the RIVM. If appropriate, the current criteria will be updated.

Secondary outcome

The secondary endpoint of this study is to evaluate whether SARS-CoV-2 IgM or IgG positive subjects are protected from re-infection with SARS-CoV-2. After 6 months of follow-up we will ask these participants whether they have experienced a second disease course of COVID-19. This second disease course of COVID-19 will be defined as the presence of COVID-19 related complaints, a hospital admission due to COVID-19, a positive PCR and/or a suspected Computerized Tomography (CT) of the lungs.

Study description

Background summary

From mid-March the Dutch government has established measures to prevent SARS-CoV-2 from spreading too fast and flatten the curve of infection rates in The Netherlands. One of the measures taken is that people need to go in quarantine after reporting a fever in combination with complaints of the upper airways, i.e. cough and/or dyspnoea. However, there is a need for validation of these current COVID-19 quarantine criteria using SARS-CoV-2 serology. In addition, this data would also be useful to evaluate whether re-infection with SARS-CoV-2 is possibl (manuscript is available via https://www.medrxiv.org/search/vogelzang).

Study objective

The primary objective of this study is to validate the current COVID-19 criteria (for non-vulnerable and vulnerable populations) with data obtained by 'De Corona Check' app and a novel SARS-CoV-2 assay (developed by Sanquin). The secondary objective of this study is to investigate whether SARS-CoV-2 IgM or IgG positive subjects are protected for re-infection with SARS-CoV-2.

Study design

This is a prospective observational study with a follow-up of 6 months. The true incidence of COVID-19, as defined by SARS-CoV-2 IgM or IgG positivity will

be compared to the number of subjects fulfilling the current COVID-19 criteria, as defined by the RIVM. In addition, after 6 months of follow-up we will evaluate whether SARS-CoV-2 IgM or IgG antibody positive subjects can go through a second disease course of COVID-19.

Study burden and risks

We will invite current users of 'De Corona Check' app to the OLVG to draw 10 ml of blood. We will also ask participants their permission to use their data from 'De Corona Check' app. SARS-CoV-2 IgM or IgG antibody positive subjects will be asked to complete an additional questionnaire after 6 months of follow-up. Therefore, the burden and risks associated with participation are negligible.

Contacts

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OLVG

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- At least 1 complete day of data-entry in 'De Corona Check' app

Exclusion criteria

- Language problems precluding the completion of the questionnaire;
- Lack of informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	2000
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-11-2020
Application type:	First submission
Review commission:	METC NedMec

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	NL73835.041.20