Longevity of specific and cross-reactive cellular responses to coronaviruses in comparison to serology in COVID-19 convalescent individuals

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

Summary

ID

NL-OMON57260

Source
ToetsingOnline

Brief title
CoviCross

Condition

- Viral infectious disorders

Synonym
coronavirus, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: TKI-LSH;Health~Holland (public-private partnership). Sponsors van het onderzoek zijn Erasmus MC en Innatoss Laboratories B.V.

Intervention

Keyword: COVID-19, Immunity, Longevity, SARS-CoV-2

Outcome measures

Primary outcome

The main study parameter in this study is the proportion of COVID-19 convalescent individuals with a detectable SARS-CoV-2-specific adaptive immune response (T-cell and antibody responses for various antigens) at different timepoints between year one and two post initial infection.

Secondary outcome

As secondary parameters in this study the quantity, phenotype and activation profile of T-cells specific for SARS-CoV-2 and HCoVs, which will be compared at different times post SARS-CoV-2 infection and vaccination.

Study description

Background summary

SARS-CoV-2 is the causative agent of a pandemic of respiratory tract disease, referred to as coronavirus disease 2019 (COVID-19). Now that several vaccines have become available, we are entering a phase in which it is crucial to understand SARS-CoV-2-specific immunity on the individual and population level. Detection of SARS-CoV-2-specific immune responses relies mostly on antibody testing. However, asymptomatic and mild cases do not always develop detectable antibody levels and specific antibodies may not be long-lived. At the same time, virus-specific T-cell responses appear long-lived, and detectable after asymptomatic infection as well as after recovery from disease. Therefore, detection of SARS-CoV-2-specific T-cells could be a valuable diagnostic marker for prior exposure to SARS-CoV-2.

Study objective

SARS-CoV-2 is related to a number of seasonal coronaviruses that have been endemic in humans for decades and usually cause *common cold* symptoms (HCoVs). Several studies have shown that SARS-CoV-2-specific T-cells can be detected in individuals never exposed to SARS-CoV-2. This likely reflects the presence of cross-reactive T-cells, i.e. T-cells induced by HCoVs that cross-recognize SARS-CoV-2. To study SARS-CoV-2-specific immunity on the individual and population level, it is of paramount importance that we are able to discriminate between T-cell responses that recognize SARS-CoV-2, HCoVs or both. To this end, we will generate and validate unique discriminatory peptide pools. Using these peptide pools, we will study the longevity of T-cell responses in comparison to antibody responses in a well-defined cohort of convalescent COVID-19 patients from the first wave of the COVID-19 pandemic.

Study design

Observational cohort study

Study burden and risks

The study participants will be asked to provide three blood samples in a period of 12 months (in total 165ml). Venepunctures will be performed by trained phlebotomists and pose a minimal risk. Participation will require three visits of max. 20 minutes each. In addition, individuals will be asked prior to each blood collection time point to answer a short list of questions to capture relevant clinical details on SARS-CoV-2 re-infections and/or vaccination.

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

• Aged at least 18 years old
• Self-reported clinical history consistent with COVID-19
• Laboratory-confirmed history of SARS-CoV-2 infection (sero-conversion)

Exclusion criteria

There are no specific criteria for subjects to be excluded from participation in this study, as long as they adhere to the inclusion criteria mentioned above.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	24-05-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25158
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77472.078.21
OMON	NL-OMON25158