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

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Virus-specific T-cell responses are more long-lived than antibody responses

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25158

Bron
Nationaal Trial Register

Verkorte titel
CoviCross

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: Department of Viroscience, Erasmus MC; Innatoss Laboratories B.V.; TKI Life Sciences & Health, Health~Holland
Overige ondersteuning: TKI Life Sciences & Health, Health~Holland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To test the hypothesis that T-cell responses are more long-lived than antibody responses, we will compare the proportion of COVID-19 convalescent individuals with detectable T-cell and antibody responses to different SARS-CoV-2 proteins. The responses will be treated as a categorical variable (positive or negative). Cut-offs for positivity of T-cell responses to the various antigens will be established based on pre-pandemic samples in a different part of the overarching CoviCross project.

We will perform a multivariate analysis of variance (MANOVA). MANOVA compares groups on a set of dependent variables simultaneously. Rather than test group differences using several separate ANOVAs and run the risk of increased familywise error (probability of one or more Type I errors), the MANOVA approach makes a single comparison and the analysis therefore does not have to be adjusted for multiple hypothesis testing.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.

Objective: SARS-CoV-2 is related to 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, 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 population: Observational cohort study

Intervention (if applicable): Not applicable

Main study parameters/endpoints: The cohort was previously established by Innatoss

Laboratories, based on diagnostic studies. The main study parameters of the proposed study are quantification and characterization of SARS-CoV-2-specific T-cells and antibody responses post-infection and/or vaccination. COVID-19 vaccination is not part of this study, volunteers will be offered vaccination through the ongoing national vaccination programs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. The study does not result in benefits to the participating volunteers.

Doel van het onderzoek

Virus-specific T-cell responses are more long-lived than antibody responses

Onderzoeksopzet

3 timepoints in total: The study participants will be asked to provide three blood samples in a period of 12 months. First timepoint was a 1 year post SARS-CoV-2 infection but pre-vaccinaton timepoint, second timepoint is a post-vaccination follow-up, third timepoint is a one year later longevity sample.

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 (irrespective of vaccination).

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

Contactpersonen

Publiek

Erasmus MC
Rory de Vries

+31642127910

Wetenschappelijk

Erasmus MC
Rory de Vries

+31642127910

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2021
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	09-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 57260
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9590
CCMO	NL77472.078.21
OMON	NL-OMON57260

Resultaten