In vitro characterization of the immune response of recovered COVID-19 patients and healthy controls to SARS-CoV-2

Gepubliceerd: 07-08-2020 Laatst bijgewerkt: 15-05-2024

This study is exploratory and no formal hypothesis is set.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20400

Bron
Nationaal Trial Register

Verkorte titel
CHDR2029

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: ISA Pharmaceuticals B.V.
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Memory T cell response as assessed by interferon-ɣ enzyme-linked immune absorbent spot (ELISpot) assay and/or enzyme-linked immunosorbent assay (ELISA) and intracellular

cytokine staining (ICS)

Toelichting onderzoek

Achtergrond van het onderzoek

The sponsor is developing a therapeutic vaccine against SARS-CoV-2, for patients recently infected with SARS-CoV-2.
Before the therapeutic vaccine will be taken into phase 1 clinical testing, the elicited immune response will determine the most suitable therapeutic candidate for further development as a therapeutic entity to treat SARSCoV2 infections

Doel van het onderzoek

This study is exploratory and no formal hypothesis is set.

Onderzoeksopzet

1 blood sample on Day 1

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Centre for Human Drug Research
I.M.C. de Visser-Kamerling

+31 71 5246 400

Wetenschappelijk

Centre for Human Drug Research
I.M.C. de Visser-Kamerling

+31 71 5246 400

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for both recovered COVID-19 patients and healthy participants
1. Participant must sign the study informed consent form prior to any study-mandated procedure indicating that he or she understands the purpose, procedures and potential risks, and is willing to participate in the study;
2. Participant is male or female and between 18 and 65 years of age, inclusive, at the time of enrollment;
3. Participant is willing and able to complete the study procedures;
4. Participant has a primary care physician at the time of enrollment;
5. Participant is not taking any immunosuppressive medication or other immunomodulating agents (including investigational drugs) for at least 3 weeks prior to study blood sampling.
Inclusion criteria for recovered COVID-19 patients only
1. Participant reports a previous positive diagnostic test result for SARS-CoV-2 infection (serological testing or viral RNA detection by PCR testing);
2. Participant had clinical symptoms of COVID-19 (including, but not limited to: cough, fever, shortness of breath, sudden onset of anosmia, ageusia or dysgeusia). The diagnosis of COVID-19 must be the most plausible cause of the reported symptoms, as deemed by the study physician;
3. Participant has recovered from COVID-19 for at least three weeks prior to study blood sampling (residual symptoms such as, but not limited to, fatigue and reduced exercise tolerance - that would not jeopardize study endpoints - are allowed at the investigator's discretion).
Inclusion criteria for healthy participants only
1. Participant is generally healthy in the investigator's clinical judgment, as determined by medical history evaluation, including no clinically significant disorder, condition, infection or disease that would interfere with the study evaluation, procedures or completion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for both recovered COVID-19 patients and healthy participants
1. Participant with a whole blood donation or loss of >500 ml within 21 days before study blood sampling;
2. Any known factor, condition, or disease that might interfere with compliance, study conduct or interpretation of the results, as deemed by the investigator.
Exclusion criteria for healthy participants only
1. Participant reports a previous positive diagnostic test result for SARS-CoV-2 infection (serological testing or viral RNA detection by PCR testing);

2. Participant developed clinically overt symptoms of COVID-19 following close contact with a proven SARS-CoV-2 positive patient, but was not tested (e.g. due to limited test capacity and regulations at that time);
3. Participant who is currently working, or has worked in an occupation with a high risk of exposure to SARS-CoV-2 (e.g. health care worker).

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 nog niet gestart
(Verwachte) startdatum:	10-08-2020
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
Not applicable

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50131
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8821
CCMO	NL74814.058.20
OMON	NL-OMON50131

Resultaten

Samenvatting resultaten
Not applicable