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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20400

Source
NTR

Brief title
CHDR2029

Health condition

COVID-19

Sponsors and support

Primary sponsor: ISA Pharmaceuticals B.V.
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

Serum IgG antibodies as measured by ELISA

Study description

Background summary

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

Study objective

This study is exploratory and no formal hypothesis is set.

Study design

1 blood sample on Day 1

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-08-2020
Enrollment:	14
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
Not applicable

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 50131
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
Not applicable