SARS-CoV-2 specific immunity in persons with a primary immune deficiency

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24202

Source
NTR

Brief title
SUNNY

Health condition

Primary Immune Deficiency

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center, Dept. of Infectious Diseases

Intervention

Outcome measures

Primary outcome

1. SARS-CoV-2 specific T-cell immunity: CD4+ T cells and CD8+ T cells against SARS-CoV-2 structural proteins (N, M and S)
2. SARS-CoV-2 specific neutralizing antibodies

Secondary outcome

None

Study description

Background summary

Goal
Research has shown that persons who are immunocompromised due to different causes, have a higher risk for a severe clinical course of COVID-19. Nevertheless, scarce data in addition to our own experience suggest that persons with a primary immune deficiency, mainly common variable immune deficiency (CVID) do not have a higher risk for a severe clinical course. In this study, we will determine the SARS-CoV-2 specific T-cell and neutralizing antibody responses in persons with a primary immune deficiency who have had COVID-19 in the past months.

Population
Persons with a primary immune deficiency who are being monitored at the Leiden University Medical Center (LUMC) of 18 years or older, who have had COVID-19

Endpoints
SARS-CoV-2 specific T-cell immunity and SARS-CoV-2 neutralizing antibodies of persons with PID who have had COVID-19 compared to persons without PID who have had COVID-19

Study objective

Persons with a primary immune deficiency do have SARS-CoV-2 specific T-cells, neutralizing antibodies or both

Study design

One time point during CVOID-19 or after having recovered from COVID-19

Intervention

None

Contacts

Public

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Eligibility criteria

Inclusion criteria

- age 18 or older
- diagnosed with primary immune deficiency and a patient at the Leiden University Medical Center
- proof of having had COVID-19 by PCR, either by GGD (municipal Health Center) of LUMC

Exclusion criteria

- vaccinated against SARS-CoV-2

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: Recruiting

Start date (anticipated):	01-02-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	16-02-2021
Application type:	First submission

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
NTR-new	NL9277
Other	METC Leiden Den Haag Delft : N L76388.058.20

Study results