Immunity against SARS-CoV-2 in immune-suppressed patients: increased risk of insufficient immunological memory or sufficient protection against re-infection? A Target to B! substudy

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- To compare the course and determinants of the SARS-CoV-2-specific humoral and cellular immune response in AID patients upon primary SARS-CoV-2 infection to that in healthy controls (HC)- To determine the seroconversion rate, magnitude and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55289

Source
ToetsingOnline

Brief title
T2B! immunity after SARS-CoV-2

Condition

- Other condition
- Autoimmune disorders
- Viral infectious disorders

Synonym
immunity, immunosuppressive medication, SARS-CoV-2 infection

Health condition

hematologische en andere B-cel gemedieerde aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: immunity, immunocompromised patients, SARS-CoV-2, vaccination

Outcome measures

Primary outcome

• Effects of systemic immunosuppressive medication on the serologic response at 28-days after the second SARS-CoV-2 vaccination

• Difference in SARS-CoV-2-specific B- and T-cell frequencies and functional phe-notype and determinants thereof

Secondary outcome

• Changes in SARS-CoV-2 IgM, IgG and IgA responses over time and determinants thereof

• Speed of mounting, the magnitude and persistence of the immune response against SARS-CoV-2 and determinants thereof

• Number of confirmed SARS-CoV-2 (re-) infections and determinants thereof.

• Change in disease activity and/or relapses of underlying autoimmune disorders

• Clinical determinants (including age and gender, disease, disease mechanism and medication) of SIAP

• Clinical determinants of patient choices and preferences related to vaccine administrations

• Differences in IgG/IgM/IgA antibodies against different SARS-CoV-2 proteins over time

• Change in disease activity and/or relapses of underlying autoimmune disorders within 8 weeks after SARS-CoV-2 infection and vaccination

• Changes in and determinants of disease activity and/or relapses in the underlying AID during the study period

• Incidence and determinations of short-term adverse events after vaccination

• Differences in and determinants of severity of SARS-CoV-2 (re-) infections.

• The number of ISP with SARS-CoV-2 IgM, IgG and IgA antibodies at baseline in patients with previously positive PCR.

• Compare early SIAP development to immunity at follow-up and development of induced immunity after vaccination

• Effects of a second booster SARS-CoV-2 vaccine (third vaccine) on serological and cellular responses in immune-suppressed patients

• Effects of a second booster SARS-CoV-2 vaccine (third vaccine) on adverse events within 7 days after vaccination, and changes in activity of underlying auto- immune disorders within 8 weeks after vaccination

Study description

Background summary

A better understanding of the maintenance of SARS-CoV-2-specific immunity after primo-infection (SIAP) is pertinent to address the risk of re-infection over

time, especially for patients with auto-immune disease (AID), including immune-suppressed patients (ISP), which may be at greater risk. In addition to this, there is uncertainty about the efficacy of the much-awaited vaccines in AID patients compared to healthy individuals as it is known for other vaccines that protection is attenuated. A better of understanding of SIAP and the effects of induced immunity by vaccination in AID patients is critical to tailor care and guidelines to maximally protect this vulnerable population.

Study objective

- To compare the course and determinants of the SARS-CoV-2-specific humoral and cellular immune response in AID patients upon primary SARS-CoV-2 infection to that in healthy controls (HC)
- To determine the seroconversion rate, magnitude and determinants of SARS-CoV-2-specific immunity after vaccination in AID patients with and without previous SARS-CoV-2 infection patients and compare to that in healthy persons with and without previous SARS-CoV-2 infection.

Study design

This is a prospective observational cohort study consisting of two phases: phase 1 starting during the pandemic up to start of phase 2 and phase 2 starting just prior to the national vac-cination campaign against SARS-CoV-2.

Study burden and risks

Participation in this study has negligible risk because the only intervention done is fingerprick or venapuncture to obtain blood. In principal, study visits will be primarily home-based and hospital visits are restricted and preferentially planned to coincide with standard clinical visits to decrease the burden for participants. There is no direct benefit for participants. Results from this project will help to increase knowledge on immunity, both after a SARS-CoV-2 infection and after vaccination, in immunosuppressed patients. This study can only be done in this population.

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

fase 1: auto-immune disease, treatment with at least one immunosuppressive medication, SARS-CoV-2 infection
fase 2/group 1:auto-immune disease
fase 2/group 2: healthy control

Exclusion criteria

Known pregnancy during study entry. Concomitant treatment with immunosuppressive medication (like chemotherapy) for cancer or organ-transplantation (including stem-cell transplantation).

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2020
Enrollment:	5350
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	19-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 23600
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74974.018.20
OMON	NL-OMON23600