T2B! immunity after SARS-CoV-2

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The main hypothesis is that specific mechanisms of action and level of immunosuppressive medication is the most important determinant of SARS-CoV-2 immunity after vaccination or infection in ISP patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON23600

Source
NTR

Brief title
T2B! immunity after SARS-CoV-2

Condition

- Autoimmune disorders

Health condition

SARS-CoV-2, auto-immune diseases,

Research involving
Human

Sponsors and support

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

Intervention

Explanation

Outcome measures

Primary outcome

- Effects of systemic immunosuppressive medication on the serologic response at 28-days after the last SARS-CoV-2 vaccination - Difference in SARS-CoV-2-specific B- and T-cell frequencies and functional phenotype 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. - 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

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 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 ISP 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 ISP is critical to tailor care and guidelines to maximally protect this vulnerable population.

Study objective

The main hypothesis is that specific mechanisms of action and level of immunosuppressive medication is the most important determinant of SARS-CoV-2 immunity after vaccination or infection in ISP patients.

Study design

serology group: baseline (prior to vaccination); 28 days after first vaccination; 28 days after second vaccination; 12 months after first vaccination cellular group: baseline (prior to vaccination); 10 days after second vaccination;28 days after first vaccination; at second vaccination; 10 days after second vaccination; 28 days after second vaccination; 12 months after first vaccination

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Patients with auto-immune disorders with or without immunosuppressive medication or healthy controls, above 18 years

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 phase:	N/A
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2021
Enrollment:	4500
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	01-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

ID: 55289
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8900
CCMO	NL74974.018.20
EudraCT	2021-001102-30
OMON	NL-OMON55289

Study results

Results posted: 08-02-2024

Actual enrolment: 3361

First publication
02-03-2022