Viro-immunological, clinical and psychosocial correlates of disease severity and long-term outcomes of infection in SARSCoV-2 - a prospective cohort study: *the VIS cohort study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON56179

Source
ToetsingOnline

Brief title
The VIS Cohort Study

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
Corona, COVID19

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: In kind AUMC;GGD / Zonmw

Intervention

Keyword: long-term outcome, SARSCoV-2, Viro-immunology, VIS

Outcome measures

Primary outcome

1: To identify socio-demographic, clinical, virological and/or host factors

predictive of disease progression

2: To investigate the induction of lasting protective SARS-CoV-2-specific

antibody (titers and breadth) and SARS-CoV-2-specific T cell responses (numbers

and quality) in relation to disease severity, clinical recovery and patient

characteristics or re-infection over time;

3: Asses the mid-term (4 weeks - 3 months post diagnosis) and long-term (until

2 year post diagnosis) sequelae of individuals who have experienced a

SARS-CoV-2 infection, particularly with respect to respiratory function,

socio-psychological outcomes and quality of life.

Secondary outcome

(4) To gain insight in the immune response after vaccination

5: To investigate influenza vaccine responses in the context of waning immunity

after prolonged absence of influenza circulation;

6: To establish a well characterised data-and biobank for future in-depth pathophysiological, immunological, host-genetic and further clinical and epidemiologic studies.

Substudy objectives

7: To investigate risk factors (demographic, clinical, virological, immunological) for SARS-CoV-2 reinfections.

8: To understand which factors determine the longevity and breadth of protective SARS-CoV-2-specific humoral and cellular immunity.

9: To determine the health impact of SARS-CoV-2 reinfections or their sequelae.

Study description

Background summary

Coronavirus disease 2019 (COVID-19) is caused by the coronavirus SARS-CoV-2 (hereafter named *COVID-19* virus) and is a rapidly spreading pandemic. Upon infection, COVID-19 is accompanied with a significant morbidity and mortality, in particular among those with comorbidities. The clinical picture in the subgroup of patients that experience severe symptoms is characterized by an exaggerated inflammatory response and ARDS (acute respiratory distress syndrome). The host and viro-immunological factors that determine which patients are at risk for the development of such severe disease are currently unknown. It is unclear how SARS-CoV-2-specific immune responses are induced and what role the innate and adaptive immune systems play in clearance of the virus and disease severity. Furthermore it is unknown if and how lasting protective immune response are induced and how the latter affect re-infection risk. In addition, mid and long-term sequelae and their determinants are not yet known.

The majority of individuals clinically recover from COVID-19 but data are lacking on the long-term effects of (re-)infection. It is unclear how

reinfections with SARS-CoV-2 are related to the durability of the SARS-CoV-2 specific immune response and what the impact of severe disease is on clinical recovery, long term pulmonary function, quality of life and psycho-social well-being.

Study objective

The overall aim of the proposed project is to establish a longitudinal cohort of adult patients who are infected with SARS-CoV-2, at different levels of disease severity, ranging from mild illness to severe and life-threatening disease requiring hospitalization and intensive care. These patients will be followed in a study for one year after initial diagnosis of infection.
This cohort will be used (1) to identify socio-demographic, clinical, virological and/ host factors predictive of disease progression, (2) to Investigate the induction of lasting protective SARS-CoV-2-specific antibody and SARS-CoV-2-specific T cell responses in relation to disease severity, clinical recovery or re-infection over time and (3) to gather insight into the clinical and socio-psychological sequelae of COVID-19. In addition, (4) to gain insight in the immune response after vaccination (5) to investigate influenza vaccine responses in the context of waning immunity after prolonged absence of influenza circulation; (6) to establish a data- and biobank for future in-depth pathophysiological, immunological, host-genetic and further clinical and epidemiologic studies. The addition of a substudy on reinfections enables to investigate (7) risk factors for SARS-CoV-2 reinfections in order to identify populations at risk for reinfections (8) determinants of the longevity and breadth of antibody- and T-cell mediated SARS-CoV-2 immunity and (9) the health impact of SARS-CoV-2 reinfections or their sequelae in order to estimate the impact on individual health and society.

Study design

The study is designed as a prospective observational cohort study. Patients are enrolled in the AUMC and the GGD Amsterdam and will be followed during the initial study for up to 2 year after diagnosis.
For the reinfections substudy, the time points of data and biological collections are: S0 (October 2022), S3 (January 2023), S6 (April 2023), S9 (July 2023), and S18 (April 2024).
In total, participants will be followed for up to 4 years after diagnosis.

Study burden and risks

Several study visits will be required (while hospitalized, at GGD or at home). Participants will be exposed to online questionnaires. In the first month, detailed information on symptoms will be assessed by the investigator. Thereafter, symptoms will be assessed monthly in a brief online questionnaire, standardized validated questionnaires on quality of life will be included.The

risk of sampling (blood draw, feces collection, nasopharyngeal swabs, saliva and brushes) is considered minimal. There is no direct benefit of participation in the study for the patient. Regarding group relatedness, the sampling is considered to be necessary since it is the only approach to accurately investigate SARS-CoV-2 (re-) infection determinants and outcomes. This knowledge will help understand risk of reinfection and risk of severe disease progression for certain subgroups of patients (elderly, comorbidities, immunodeficiencies etc), contributing to future guidelines and protocols aimed at preventing spread and reducing severity of illness.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- informed consent documented by signature
- age between 16 - 85 years
- sufficient understanding of Dutch or English

Exclusion criteria

- Unlikely to comply with the study procedures, as deemed by the recruiting research doctor/nurse
- mental disorder that in the view of the investigator would interfere with adherence to the study procedures, or the decision to participate in the study.
- Investigators or otherwise dependent persons
- living in long term care facility

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-05-2020
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	08-05-2020
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
CCMO	NL73759.018.20