Isolation of COVID-19-Specific neutralizing Antibodies from COVID-19 patients for therapeutic and prophylactic use

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

Summary

ID

NL-OMON55316

Source
ToetsingOnline

Brief title
The COSCA study

Condition

- Viral infectious disorders

Synonym
Coronaviral infection, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: De studie wordt gefinancieerd uit de winst reserve van de afdeling medische microbiologie.

Intervention

Keyword: COVID-19, neutralizing antibody, SARS-CoV-2

Outcome measures

Primary outcome

For objective 1, the main endpoints are the percentage COVID-19 spike protein positive memory B cells and the neutralization potency of monoclonal antibodies derived from COVID-19 spike protein positive memory B cells. For objective 2 the main endpoint are the percentage Coronavirus (CoV) cross-reactive memory B cells and the neutralization potency and breadth of monoclonal antibodies derived from CoV cross-reactive memory B cells.

Secondary outcome

NA

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 epidemic. Upon infection, COVID-19 is accompanied with a significant morbidity and mortality among those who are infected. Currently, there are no specific treatment options available. In Ebola virus, respiratory syncytial virus (RSV), rabies and others neutralizing antibodies were effective in treatment and prevention of infection. In combination with the low viral diversity of COVID-19 and known antibody responses in COVID-19 patients, we hypothesize that the isolation of COVID-19-specific antibodies may provide an avenue for prevention and treatment of COVID-19.

Study objective

The primary objective (1) of the proposed study is to isolate and characterize neutralizing monoclonal antibodies from patients who recovered from COVID-19 infection. The secondary objective (2) is to isolate and characterize monoclonal antibodies with broadly neutralizing activity against other coronaviruses or SARS-CoV-2 variants.

Study design

Study design: The study is designed as an observational study
Methods: In patients who were diagnosed with a COVID-19 infection, at 3-8 weeks after occurrence of first symptoms, a sample of 65 mL blood will be drawn. The blood samples will be transferred to and handled in the HIV lab of the department of medical microbiology according to standardized protocols and as part of ongoing work on antibody responses in HIV-1 infection. In case the nasopharyngeal swab of diagnosis is not readily available, a new nasopharyngeal swab is performed early in the disease.

Study burden and risks

The risk of sampling (one blood draw) 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 isolate COVID-specific monoclonal antibodies that may in the future be a potential source for therapy in similar patients.

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

-written informed consent to participate in the study and store samples
-age between 18 and 75 years
- PCR confirmed SARS-CoV-2 infection
- able to visit the Amsterdam UMC, location AMC 3-8 weeks after onset of COVID-19 symptoms. In the absence of symptoms, patients will visit the Amsterdam UMC, location AMC 3-8 weeks after PCR confirmation. A home visit by the study team is a possibility when the patient is unable to travel to the Amsterdam UMC.

Exclusion criteria

-mental disorder that in the view of the investigator would interfere with adherence to the treatment or the study procedures, or the decision to participate in the study.
-use of immunosuppressive medication (equivalent of > 7.5mg prednisolone / day). Note: Patients with only a short course of immunosuppressive medication can still participate.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2020
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2022

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

No registrations found.

In other registers

Register	ID
CCMO	NL73281.018.20