Immunological, Mental and Physical After-effects of COVID-19 infection

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Primary research objectiveTo describe the recovery of physical and mental quality of life after a COVID19 infectionSecondary research objectives:1. Investigate the incidence of SARS-CoV2 re-infections during follow-up expressed in number of cases...

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

Summary

ID

NL-OMON55044

Source
ToetsingOnline

Brief title
IMPACD-2 study

Condition

- Viral infectious disorders

Synonym
COVID19, infection with SARSCoV2

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COVID19, quality of life, re-infection, serology

Outcome measures

Primary outcome

recovery of quality of life based on the results of questionnaires after COVID19 infection

Secondary outcome

1. occurrence of new infections with SARSCoV2 within year after admission with COVID19 infection, based on self-report, confirmed with (patient approved) requested information about the confirmation of that infection in another laboratory

2.outcomes of lung function studies in patients who still had an impaired lung function test after 3 months and who are being followed up at the outpatient clinic for lung diseases at 6, 12 and 18-24 months after COVID19 infection

3.occurrence of death within a year after COVID19 infection and record of cause of death (retrieved via GP, with prior patient consent)

4.height of concentration of antibodies against SARSCoV2 at 6 and 12 months after admission with COVID19 infection

Study description

Background summary

In the first half of 2020, the Netherlands was hit by the first wave of COVID19, with many patients receiving care for this at the OLVG. In a specially activated outpatient clinic, more than 450 people were seen, as part of aftercare, who had experienced this infection.
It is currently unclear whether, and if so, to what extent people will be left with residual damage after a COVID19 infection. Furthermore, there is still uncertainty about the duration and effectiveness of the acquired immunity, which should protect the patient against possible new infections with SARS-CoV2. When a so-called 2nd wave COVID19 occurs, these patients fear that they could become ill again
Through this study protocol, we want to follow up this patient group prospectively for a period of at least 1 year, with a focus on quality of life and its recovery (both mental and physical) in the follow-up period, the occurrence of a new infection. with SARS-CoV2, as well as for the preservation of the specific anti-SARS-CoV2 antibodies that developed during the COVID19 period.

Study objective

Primary research objective
To describe the recovery of physical and mental quality of life after a COVID19 infection

Secondary research objectives:
1. Investigate the incidence of SARS-CoV2 re-infections during follow-up expressed in number of cases per 100 person-years of follow-up
2. Investigate any further improvement in lung function at 6, 12 and 18-24 months
3. Investigate mortality and cause of death after recovery of 1st COVID19
4. Investigate the course of antibody response against SARS-CoV2 after COVID19
5. Analyze possible association of the various patient characteristics (sex, age, comorbidity, medication use, intoxications and severity of COVID19) and the primary and secondary outcomes at 6, 12 and 18-24 months

Study design

All potential participants were seen at the outpatient clinic around 3 months after their COVID19 infection as part of the COVID19 care program. Around that time, the consequences of the COVID19 were systematically recorded during the care process, with specific attention to mental and physical well-being (by means of questionnaires) as well as to damage to the lung (by means of lung function and X-ray examination). All patients were investigated for antibody development by blood sampling around 4 weeks after disease presentation. Some of the patients remained in the care of a lung specialist if there was a

reduced lung function and / or radiological abnormalities were still present, the other part was referred back to primary care. All patients were asked if they could be approached for a prospective follow-up study
During a prospective follow-up study, in case of new symptoms, all patients will be advised to be re-tested for infection with the SARS-CoV2 virus by a general practitioner and / or municipal healthcare service, and to report a positive finding to the OLVG research team. Furthermore, at month 6, 12 and 18-24 after the start of the care process at the time of the COVID19 period (T = 0), the quality of life will be evaluated by means of validated questionnaires (SF36, HADS, PCL-5 and ICI), as well will they be asked about clinical events that have occurred. With prior permission, further information may be obtained from their general practitioner with regard to diagnoses made or if the patient no longer responds to evaluation requests. In addition, a new serum tube will be taken from all patients at 6 and 12 months to determine the antibody titer against SARS-CoV2; this result will be compared with the values **at T = 0 and T = 5 weeks.
Of all patients who remained in care with a pulmonologist after 3 months, change (improvement?) In lung function and radiological abnormalities will be analyzed

Study burden and risks

The burden is limited, since for all participants the only additional burden is a venipuncture taken twice to obtain a serum sample (with the risk of bruising), as well as the fulfillment of the above-mentioned questionnaires (also twice).
Through the study, participants are actively involved in acquiring new information on the new infection COVID19, actively considering their own health and being informed about the degree of permanent sero-immunity (much of which is still unclear at this point)

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

all patients who visited the postCOVID outpatient clinic in the OLVG 3 months after their COVID19 infection

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	22-09-2020
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL75063.100.20