Long-term consequences of more severe COVID-19 infections (complicated respiratory tract infections), in patients managed in general practice and risk factors for a delayed recovery

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The primary objective of this study is to determine the difference in the health-related quality of life (determined by SF-36) between patients with and without an established SARS-CoV-2 infection in a 12 month follow-up period in patients managed...

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

Summary

ID

NL-OMON52826

Source
ToetsingOnline

Brief title
PROCOVID-19

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
respiratory tract infection covid-19

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: COVID-19, general practice, long term consequences, respiratory tract infection

Outcome measures

Primary outcome

The main study parameter is the difference in the health-related quality of life (determined by SF-36) between patients with and without an established SARS-CoV-2 infection in a 12 month follow-up period and risk factors that influence recovery.

Secondary outcome

Secundairy objectives are to assess in patients who were suspected of having serious COVID-19 infections: differences in the different sections of the SF-36 from index consultation to 12 months after the index consultation, the severity and duration of physical complaints and risk factors that influence recovery, the number of episodes of respiratory infections requiring antibiotic prescription, exacerbations of chronic disorders, hospital referrals, mortality within 12 months, number of contacts with GP, the extent of mental complaints or mental disorders and impact on daily activities.

Objectives of the substudy are to assess the presence and severity of long-lasting physical and psychological symptoms after COVID-19 and NeuCD10 expression in blood samples of subjects (using flow cytometry) 24-29 months after a confirmed COVID-19 infection.

Study description

Background summary

Much is unknown about long-term prognosis of patients that are treated in primary care with complicated COVID-19 respiratory tract infections. Complicated COVID-19 respiratory tract infections in hospitalized patients can cause long lasting lingering symptoms, both somatically and psychologically. The long term impact of complicated COVID-19 respiratory tract infections managed at home is still unknown. General practitioners, however, frequently report patients with long-term symptoms. Knowledge on the prognosis of patients with a complicated COVID-19 respiratory tract infection and identifying patients at risk for long-term symptoms is important in order to improve follow-up and adequate support of these patients. Ongoing fundamental research focusses on the role of cellular markers on the prognosis of patients with complicated COVID-19 respiratory tract infections. Amongst other markers, neutrophil CD10 (neuCD10) has been found to be a relevant cellular marker. Expression of neuCD10 is decreased in both hospitalized and non-hospitalized patients with a complicated COVID-19 respiratory tract infection. NeuCD10 poses the function to reduce the level of bradykinin, a key enzyme in the development of pulmonary edema. Whether these reduced neuCD10 levels are still present after disease resolution and whether neuCD10 levels correlate with long-term symptoms has yet to be determined.

Study objective

The primary objective of this study is to determine the difference in the health-related quality of life (determined by SF-36) between patients with and without an established SARS-CoV-2 infection in a 12 month follow-up period in patients managed in general practice with more severe suspected COVID-19 infections (complicated respiratory tract infections), and to determine risk factors that influence recovery.
Secundairy objectives are to assess in patients who were suspected of having serious COVID-19 infections: differences in the different sections of the SF-36 from index consultation to 12 months after the index consultation, the severity and duration of physical complaints and risk factors that influence recovery, the number of episodes of respiratory infections requiring antibiotic prescription, exacerbations of chronic disorders, hospital referrals, mortality within 12 months, number of contacts with GP, the extent of mental complaints or mental disorders and impact on daily activities.
Additionally, the objective of the sub-study is to determine neuC10 expression in subjects more than two years after a complicated at home COVID-19 respiratory tract infection to explore whether neuCD10 levels are still decreased and whether neuCD10 levels are related to long-lasting complaints

after a more severe COVID-19 infection managed in primary care.

Study design

Observational study

Study burden and risks

Risks/disadvantages: Risks for the participants are negligible. The only invasive procedures performed are one or two venipunctures, which are low risk procedures. Moreover, the second venepuncture will only be performed in a subset of the included subjects (those with positive SARS-CoV-2 serology). Besides, it will take time (about 30-45 minutes) from participants to complete the follow-up interviews every 3 months, for a period of 1 year. The additional questionnaire of the substudy will take even less time (10-20 minutes). The burden of completing these questionnaires is estimated to be low, as the time interval is relatively long and the nature of the questions not burdensome. Benefits: Participant can, if they whish, be informed on their SARS-CoV-2 status at the end of the study. There are no compensations for participants. In summary: benefits are in balance with disadvantages of the study. Risks for participants are negligible.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- At least 18 years of age
- History of a complicated respiratory tract infection (ICPC code R81 pneumonia or R02 dyspnea, R05 cough, R74 respiratory tract infection R83 other respiratory tract infection or R78 bronchitis for which a course of antibiotics was started), between March 1st and June 1st 2020 in primary care

In order to be eligible to participate in the substudy on neuCD10 expression, a subject must meet all the following criteria:
- Positive SARS-CoV-2 study-serology
- Written consent to be approached for additional research

Exclusion criteria

- Life expectancy of <1 year,
- Hospitalisation in the previous 14 days before the index consultation
- Not capable of performing telephone interviews
- Hospitalisation within 14 days after the index consultation

A potential subject who meets any of the following criteria will be excluded from participation in the substudy on neuCD10 expression:
- Death during follow-up

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2020
Enrollment:	274
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-12-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-03-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-05-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL74467.041.20
Other	NL8729

Study results

Date completed: 22-08-2022

Actual enrolment: 322

Summary results
Trial is onging in other countries