Primary care Research on Outcomes of COVID-19

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28610

Source
Nationaal Trial Register

Brief title
PRO-COVID-19

Health condition

complicated respiratory tract infections, COVID-19

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Quality of life (SF-36)

Secondary outcome

episodes of respiratory infections requiring antibiotic prescription, number of contacts with

GP, exacerbations of chronic disorders, hospital referrals, mortality within 12 months, severity and duration of physical complaints, risk factors for delayed clinical recovery, mental complaints or mental disorders, exercise tolerance.

Study description

Background summary

Introduction: While we learn now that complicated COVID-19 respiratory tract infections in hospitalised 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. Knowledge on the prognosis of patients with a complicated COVID-19 respiratory tract infection is important in order to improve follow-up and adequate support of these patients.
Methods: 274 patients with a complicated respiratory tract infection, presenting at the GP between March 1 and June 1 2020 are eligible for inclusion. After informed consent, a venous blood sample for SARS-CoV-2 serology will be taken. Follow-up on patients is performed every 3 months with SF-36 by telephone. Besides, follow-up will focus on signs, symptoms, use of medication, contacts with health care professionals, dyspnea score by Medical Research Council dyspnea questionnaire, exercise tolerance, daily activities and quality of life assessment by SF-36.
12 months after the index consultation extraction of data from medical files of included subjects will take place on: contacts with the health centre and the indication for contact, signs and symptoms, additional testing for possible COVID-19 related complaints (e.g. cough, dyspnea, chest pain, fatigue, impaired exercise tolerance), use of medication, referrals to other health care professionals including psychologist or psychiatrist, outcomes on treatment or diagnostic procedures outside the health centre and mortality.

Study objective

Patients with respiratory tract infections fromo COVID-19 experience more often long lasting complaints

Study design

3-6-9-12 months after consulting the GP

Intervention

n.a.

Contacts

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Eligibility criteria

Inclusion criteria

Patients at least 18 years of age, with a history of a complicated respiratory tract infection, between March 1st and June 1st 2020 in primary care, who were not admitted to the hospital.

Exclusion criteria

Patients with a life expectancy of <1 year, patients who were hospitalized in the previous 14 days before the index consultation at the COVID-19 centre, patients not capable of performing telephone interviews, patients who were hospitalised within 14 days after the index consultation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2020
Enrollment:	274
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8729
Other	METC UMCU : volgt

Study results