COVID-19 Follow-up care paths and Long-term Outcomes Within the Dutch health care system: a combined rehabilitation, pulmonary, and intensive care perspective

No registrations found.

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

Summary

ID

NL-OMON23671

Source
Nationaal Trial Register

Brief title
CO-FLOW

Health condition

COVID-19

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: ZonMw; kickstart funding: Erasmus MC, Rijndam Rehabilitation, Laurens

Intervention

Outcome measures

Primary outcome

Pulmonary function, fitness, mobility, physical activity, cognitive function, psychological function

Secondary outcome

Health care paths, health care utilization, productivity, quality of life, participation, patient satisfaction

Study description

Background summary

Rationale: The world is overwhelmed by COVID-19, a new respiratory infectious disease. This new disease and surreal situation are expected to cause severe and long-lasting physi-cal, cognitive and psychological consequences, affecting participation and health-related quality of life. After hospitalization, many patients may need inpatient treatment in a rehabilitation or geriatric center, while others may be able to go home with outpatient rehabilitation. Health care paths and long-term functional outcomes after COVID-19 are not known yet. Knowledge on the extent and predictors of recovery after hospitalization in patients with COVID-19 is urgently needed, and will facilitate optimization of triage and rehabilitation of COVID-19 patients and comparable (future) infectious diseases.
Objective: The aim of this study is to set up a registry and to systematically study the long-term outcomes of patients with COVID-19 who survived hospitalization in the Rotterdam Rijnmond area.
Study design: Multicenter prospective cohort study with a 2-year follow-up period. Data registration as part of regular care takes place in rehabilitation centers and nursing homes (at admission and discharge) and during regular out-patient visits at 3 and 6 months. Additional measurements predominantly concern long-term measurements after 12 and 24 months post-discharge.
Study population: Patients diagnosed with COVID-19, within 3 months post-discharge, aged 18 years and older.
Intervention (if applicable): Not applicable.
Main study parameters/endpoints: Physical, cognitive, and psychological functioning, using non-invasive clinical tests and online questionnaires.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The registry is set up for patients with COVID-19 and is therefore group-related. Data are copied from patient records and additional measurements are non-invasive and minimally physically demanding. Completion of questionnaires and additional measurements require a certain time investment from patients and might lead to temporary fatigue. Yet, by providing frequent breaks and a maximum duration of 60-84 minutes per session for online

questionnaires and a maximum duration of 40-45 minutes per session for clinical tests, we aim to minimize the burden for patients. Participants will gain more insight in their recovery.

Study objective

The aim of the CO-FLOW study is to set up a registry and to systematically study the long-term outcomes of patients with COVID-19 who survived hospitalization in the Rotterdam-Rijnmond region, by recording data from usual care and collecting additional data over a 2 years period. Based on current reports, we expect that recovery from COVID-19 will take a long time and that COVID-19 may result in long-term disability.

Study design

3, 6, 12, 24 months post hospital discharge

Contacts

Public
Erasmus MC
Majanka Heijenbrok-Kal

+31102412412
Scientific
Erasmus MC
Majanka Heijenbrok-Kal

+31102412412

Eligibility criteria

Inclusion criteria

• COVID-19 diagnosis (based on positive PCR or multidisciplinary team decision based on symptoms and CT or positive serology);
• requiring and surviving hospitalization;
• within 6 months post hospital discharge;
• patient or relative has sufficient knowledge of Dutch or English language.

Exclusion criteria

• age< 18 years;
• incapacitated subjects.

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:	Recruiting
Start date (anticipated):	01-07-2020
Enrollment:	500
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	NL8710
Other	METC Erasmus MC : MEC 2020-0487

Study results