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

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23671

Bron
Nationaal Trial Register

Verkorte titel
CO-FLOW

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: ZonMw; kickstart funding: Erasmus MC, Rijndam Rehabilitation, Laurens

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

3, 6, 12, 24 months post hospital discharge

Contactpersonen

Publiek

Erasmus MC
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• age< 18 years;
• incapacitated subjects.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8710
Ander register	METC Erasmus MC : MEC 2020-0487

Resultaten