Pulmonary damage after hospitalization for acute COVID-19, an exploratory prospective cohort study.

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

Summary

ID

NL-OMON54891

Source
ToetsingOnline

Brief title
Pulmonary damage after acute COVID-19.

Condition

- Viral infectious disorders
- Pulmonary vascular disorders

Synonym
COVID-19; coronavirus

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COVID-19, damage, pulmonary

Outcome measures

Primary outcome

The primary objective of the study is to determine types and prevalence of residual pulmonary damage after hospital admission for acute COVID-19 at 3 and 12 months follow-up.

Secondary outcome

1. To determine clinical and imaging parameters in the acute phase of COVID-19 that may predict lung damage (including pulmonary perfusion abnormalities) at 3 and 12 month follow-up

2. To determine which types of damage remain after 1 year

3. To correlate the amount and type of pulmonary damage with the clinical parameters 3 and 12 month follow-up

4. To determine the value of d-dimer levels and YEARS criteria at 3 months for prediction of pulmonary perfusion abnormalities

Study description

Background summary

The rapid spread of the novel *severe acute respiratory syndrome coronavirus 2* (SARS-CoV-2), has led to an ongoing pandemic of coronavirus disease 2019 (COVID-19). In the Netherlands, patients were mainly admitted to hospitals because of moderate to severe symptoms of the disease, usually due to substantial pulmonary involvement. The first wave of acute COVID-19 has passed but patients who were admitted to hospitals, and especially those admitted to an intensive care unit, may show a prolonged period of convalescence with mounting evidence of potentially permanent lung damage (**). Such damage has

been reported to be scarring and fibrosis, but sequelae of pulmonary thrombotic or thromboembolic events may also be present. Little is known about the prevalence and extent of such long-term lung damage in formerly hospitalized patients with known lung involvement during their acute phase. There is also a need for understanding factors that contribute to chronic damage and identify targets for prevention or treatment of long-term debilitating disease.

Study objective

The primary aim of this study is to determine types and prevalence of residual pulmonary damage after hospital admission for acute COVID-19. In particular, we aim at determining the prevalence of clinically *silent* pulmonary perfusion abnormalities and establish the connection between current complaints and lung damage as well as the relation between clinical factors during hospitalization and residual lung damage. The ultimate goal is to find predictors, modifiable by treatment during or after the hospital stay, that effect long-term outcome positively. With this study we aim at better understanding of the chronic phase of the disease and of how adverse outcomes might be prevented.

Study design

Prospective cohort study of patients suffering of COVID-19.

Study burden and risks

The patient will not benefit directly from participation to the study unless a treatable abnormality is diagnosed. We expect benefits at a group level for new patients should potential interventions emerge as a result of this study. CT angiography holds a very low risk of allergic events due iodinated contrast. The radiation exposure is such that EU dose reference levels for chest CT (indicated in the vast majority of this group) are met.

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

1. Patients eligible for post-COVID-19 care program
2. Written informed consent from patient or legal representative
3. CT during admission with CO-RADS >< = 3 or Laboratory confirmed (PRC of serologic) diagnosis of COVID-19

Exclusion criteria

1. Age <18 years
2. Pregnancy
3. Subjects with a history of allergy or intolerance to iodinated intravenous contrast media
4. Subjects with pre-existent severe renal impairment (creatinine clearance less than 30 mL/min/1.73m^2)
5. Subjects using therapeutic anticoagulation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2020
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	02-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-05-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL74223.091.20