

PULmonary DAMage after hospitalization for acute COvid-19 (PULDAMCO), an exploratory prospective cohort study

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23357

Bron

Nationaal Trial Register

Verkorte titel

PULDAMCO

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: Radboudumc

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Prevalence of residual lung damage (per type) at 3 and 12 month
- Estimated percentage of lung parenchyma affected by various types of diffuse lung damage (e.g., ground glass, consolidation, perfusion abnormalities)
- Number of lung segments affected by focal lung damage (e.g., traction bronchiectasis, residual lung emboli)
- Predictors of pulmonary damage after acute COVID-19

Toelichting onderzoek

Achtergrond van het onderzoek

Included patients will undergo a CT angiography instead of routine chest imaging after 3 months to be able to assess all types of pulmonary damage, including perfusion abnormalities, and a low-dose CT after 12 months to establish chronicity of pulmonary damage.

Doel van het onderzoek

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 affect 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.

Onderzoeksopzet

3 months and 12 months after acute COVID-19

Onderzoeksproduct en/of interventie

CT angiography at 3 months and chest CT low dose at 12 months after acute COVID-19 infection

Contactpersonen

Publiek

Radboudumc
Bram van den Borst

024-3611111

Wetenschappelijk

Radboudumc
Bram van den Borst

024-3611111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Hospital admission for COVID-19
- CT during admission with CO-RADS ≥ 3
- Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age < 18
- Pregnancy
- Renal failure (MDRD < 30 ml/kg/1,73m²)
- Allergic reaction to iodine containing intravenous contrast media

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	07-07-2020
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	07-07-2020
Soort:	Eerste indiening

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	NL8765
Ander register	CMO Regio Arnhem-Nijmegen : 2020-6637

Resultaten