Precision Medicine for more Oxygen - COVID-19 extension

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A. Pulmonary and extra-pulmonary damage assessed by imaging techniques at t = 3 months and t = 12 months after SARS-COV2 infection can be associated with clinical parameters, biomarkers, and the exposome. B. Personalized counselling...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28553

Bron
Nationaal Trial Register

Verkorte titel
P4O2 COVID-19 extension

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: Health~Holland, Boehringer Ingelheim, Breathomix, Fluidda, Ortec Logiqcare, Philips, Quantib-U, Smartfish, SODAQ, Thirona, Novartis, TopMD, Amsterdam UMC, UMC Utrecht, Universiteit Utrecht, Maastricht University, University Medical Center Groningen.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A. To assess pulmonary and extra-pulmonary damage (with imaging techniques), complaints (e.g. fatigue and Quality of Life) and other signs of disease (both clinical signs and multi-omics biomarkers) in the year after infection in ex-COVID-19 patients.
B. To assess whether a personalized counselling intervention on quality of dietary intake and level of physical activity can improve general health and decrease complaints and signs of disease (both pulmonary and extrapulmonary).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
According to the World Health Organization, lung diseases are among the deadliest diseases worldwide and lead to extremely debilitating symptoms and loss of quality of life and productivity. The recent outbreak of COVID-19 introduces many questions, one of them being the long-term effects of the disease. It is now suggested that COVID-19 survivors might be at higher risk for developing long-term reversible or perhaps irreversible lung damage.

Objective:
The Precision Medicine for more Oxygen (P4O2) program aims to identify treatable traits and innovative personalized therapeutic strategies to both prevent progression of early stage lung damage and to reverse established lung damage by stimulating repair in order to reduce burden of disease and to increase quality of life. This is the COVID extension of the original P4O2 project. The aim is to understand which patients will develop chronic lung disease following infection with SARS-COV2 and to find phenotypes. Therefore, there will be state of the art chest CT analyses, multi-omics analysis, exposome measurements, and a personalized intervention.

Study design:
Multi-centre prospective observational study including a nested intervention study.

Study population:
100 positive or highly suspected ex-COVID-19 patients, 40-65 years old. Patients will be recruited from post-COVID-19 outpatient clinics.

Intervention:
The efficacy of a personalized counselling intervention will be investigated in a nested study. Half of the patients will receive a personalized counselling intervention based on dietary quality and physical activity, which will consist of individual, group and educational sessions. Furthermore, this group will voluntary be provided with additional tailored nutritional support. The other half of the group will serve as control group and will not receive personalized counselling or nutritional support. However, this group might participate in the educational sessions (voluntary).

Main study parameters/endpoints:

A) Lung damage assessed by chest CT scans at approximately t = 3 months and t = 12 months after SARS-COV2 infection and the association of this damage with clinical parameters, biomarkers, and the exposome.
B) Difference in EQ-5D Index Score between intervention and control groups at t = 12 months after SARS-COV2 infection.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Patients will benefit from participation since they receive additional attention for their situation. This study adds to the general clinical follow-up by performing additional analyses on the chest CT scans, by performing extra analyses on biological samples (urine, blood, faeces, nosebrush, breath), and by performing analyses of their exposure to environmental factors that might influence their recovery. They also use a Garmin watch to track physical activity, which might directly help them to improve their lifestyle. All patients will be invited to participate in the educational sessions (also the control group), in which they will receive suggestions to improve their general health. Risk and inconveniences are limited to the time investment associated with the measurements. The measurements will therefore be performed at the same day of the 2 out-patient clinical visits and will approximately take 90 minutes per visit. The measurements include various non-invasive measurements, as well as minor invasive blood sampling (48 ml) and nose brush, as well as an additional CT scan for part of the group. Study visits will be combined with already scheduled regular care outpatient visits.

Doel van het onderzoek

A. Pulmonary and extra-pulmonary damage assessed by imaging techniques at t = 3 months and t = 12 months after SARS-COV2 infection can be associated with clinical parameters, biomarkers, and the exposome.
B. Personalized counselling intervention on quality of dietary intake and level of physical activity can improve general health and decrease complaints and signs of disease after SARS-COV2 infection (both pulmonary and extrapulmonary).

Onderzoeksopzet

Visit 1: 3 months post discharge after COVID-19 hospitalisation
Visit 2: 9 months after visit 1.

Onderzoeksproduct en/of interventie

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Contactpersonen

Publiek

Amsterdam UMC, location AMC
Job van Bragt

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age: 40-65 years.
- Proven ex-COVID-19: Positive PCR/serology for SARS-CoV2 or CORADS score 4/5.
- Able to provide informed consent.
- Access to internet (either at home or via relatives/friends).
- Understanding of Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inability to provide informed consent.
- History or suspicion of inability to cooperate adequately.
- Participation in any other study involving investigational or marketed products concomitantly or within four weeks prior to entry into the study or during the study.
- Investigator’s uncertainty about the willingness or ability of the patient to comply with the protocol requirements.
- Patients with terminal illness.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-04-2021
Aantal proefpersonen:	100
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:	19-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52166
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9419
CCMO	NL74701.018.20
OMON	NL-OMON52166

Resultaten