Precision Medicine for more Oxygen - COVID-19 extension

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28553

Source
NTR

Brief title
P4O2 COVID-19 extension

Health condition

COVID-19

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: 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.

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

- To determine the course of lung damage and complaints due to SARS-COV2 infection.
- To identify different phenotypes in ex-COVID-19 patients.
- To determine the influence of the exposome (environmental exposure) to lung damage and complaints in ex-COVID-19 patients one year post infection.
- To define different exposome-based groups at risk to develop lung damage after SARS-COV2 infection and subsequent hospitalisation.
- To assess the ability to use imaging techniques to detect lung damage in ex-COVID-19 patients without clear complaints.
- To determine whether SARS-CoV-2 infection triggers the onset of ME/CSF.
- To assess what risk factors are associated with the development of ME/CSF in ex-COVID-19 patients.

Study description

Background summary

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.

Study objective

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).

Study design

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

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).

Contacts

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-04-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52166
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results