Precision Medicine for more Oxygen - COVID-19 extension

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Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON52166

Source
ToetsingOnline

Brief title
P4O2 COVID-19 extension

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
corona, COVID19

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Boehringer Ingelheim,Fluidda,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,Ortec Logicqare,Philips,Smartfish

Intervention

Keyword: COVID19, Precision Medicine, Prevention, Respiratory Medicine

Outcome measures

Primary outcome

A) Lung damage assessed by CT scans at approximately t = 3-6 months and t = 12-18 months after SARS-COV2 infection and the association of this damage with biomarkers and the exposome.

B) Difference in EQ-5D Index Score between intervention and control groups at t = 12 months after SARS-COV2 infection.

Secondary outcome

- Change in CT scan assessed lung damage between t = 3-6 months and t = 12-18 months.
- The development of symptoms fulfilling the International Consensus Criteria (ICC) for ME/CSF diagnosis.
- Quality of life measure by EuroQol-5D.
- Fatigue measured by Checklist individual strength (CIS).
- Body height and weight to calculate the body mass index (BMI).
- Body composition by bioelectrical impedance analysis (BIA).
- Dietary intake by a 24h food diary
- Physical activity by accelerometry
- Motivational profiling questionnaire (self-determination theory questionnaire (SDT))

- Psychosocial functioning questionnaire (HADS)

- (Change in) exhaled breath profile assessed by eNose and GC-MS

- Lung function assessed by spirometry, diffusion capacity, maximal inspiratory

pressure (MIP) and maximal expiratory pressure (MEP)

- (Change in) transcriptome, genome, epigenome, metabolome and microbiome.

Study description

Background summary

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.

Study objective

Therefore, 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 CT analyses, multi-omics analysis, exposome measurements, and an intervention.

Study design

Multi-centre prospective observational study including a nested intervention study.

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 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).

Study burden and risks

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 CT scans, by performing extra analyses on biological samples (urine, blood, faeces, nose swab, 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 will be combined with already scheduled regular care outpatient visits.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

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

for healthy volunteers:
- age 18-65
- For the recovered healthy volunteers: proven ex-COVID-19: with a positive PCR / serology for SARS-CoV2Able to provide informed consent
- 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)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-05-2021
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	16-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28553
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74701.018.20
OMON	NL-OMON28553