Post-COVID-Health study: Multidimensional health status of COVID-19 survivors one year after a SARS-CoV-2 infection

Published: 16-09-2021
Last updated: 21-12-2024

The overall aim of this study is to assess the multidimensional health status of COVID-19 survivors one year post-infection using validated subjective and objective measures.

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

Summary

ID

NL-OMON54082

Source
ToetsingOnline

Brief title
Post-COVID-Health study

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
Coronavirus

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Het coronafonds Noord-Limburg + ABR Prof. Annemie Schols

Intervention

Keyword: COVID-19, Long-term consequences, Multidimensional health

Outcome measures

Primary outcome

Subjective multidimensional health status (EQ-5D)

Secondary outcome

Multidimensional health outcomes:

- Physiological and metabolic health

• Lung function by pre- and post-bronchodilator spirometry;

• Diffusion capacity using the single breath method;

• Persistent lung damage (CT-scan);

• Body composition by dual-energy X-ray (DEXA)-scan en CT-scan;

• Fasted resting energy expenditure by indirect calorimetry (ventilated hood);

• Cardiometabolic health by determination of the parameters of the metabolic

syndrome:

o Resting blood pressure

o Waist circumference

o Fasted glucose level (blood)

o Fasted high-density, low-density and total lipoprotein levels (HDL and LDL)

(blood)

o Fasted triglycerides (blood)

• Inflammatory status (blood)

- Physical capability

• Exercise capacity by the six-minute walking test and a cardiopulmonary cycling exercise test;

• Respiratory muscle strength by inspiratory and expiratory mouth pressure;

• Upper extremity muscle strength by measuring handgrip strength;

• Lower extremity muscle strength by measuring isometric muscle strength using the Biodex;

• Mobility using the short physical performance battery and all individual items;

• Physical activity level by accelerometry.

- Cognitieve functie:

• Montreal Cognitive Assessment (MOCA);

• Cognitive failure questionnaire (CFQ);

- Neurosensory function

• Dietary intake by a food diary

• Smell and taste using the Taste Strips *filter paper disc method* and the Sniffin Sticks threshold test, respectively as well as the taste and smell function questionnaire;

- Psychosocial well-being

• Anxiety, depression and stress using:

o The hospital anxiety and depression scale (HADS)

o Perceived stress scale (PSS)

- Social well-being

• Social support using the multidimensional scale of perceived social support

(MSPSS) and the loneliness scale (LS).

- Patient reported outcomes

• Dyspnea using the modified medical research council (mMRC)

• Fatigue using the Checklist Individual Strength (CIS)

• Sleep quality using the Pittsburgh Sleep Quality Index (PSQI)

• General pain using the Visual Analogue Scale (VAS)

- Medical history (including treatment during SARS-CoV-2 infection);

- Treatments/therapies after SARS-CoV-2 infection

- Vaccination for COVID-19;

- Re-infection with COVID-19;

- Medication use;

Subgroup analysis related to METC 2020-2230

Only in case a chest-CT scan has been obtained during screening for SARS-CoV-2 or during regular care follow-up visits and only in case this CT-scan meets the requirements for reliable extrapulmonary quantifications of muscle and adipose tissue cross sectional area, the chest-CT scan obtained in the current study will be compared to previous CT-scans in order to assess pulmonary and extrapulmonary changes. In this case, the chest CT-scans obtained for COVID-19 reasons will be extracted from medical records and analyzed according to the same protocol as the current study, unless this has already been done in METC 2020-2230.

Study description

Background summary

Within the Netherlands, more than 1 million people have been infected with SARS-CoV-2, also known as COVID-19. Although the mortality rate is considerable, the vast majority of COVID-19 patients survive the infection. Preliminary findings show that a majority of COVID-19 survivors still experience health problems 3 months after the infection, including reduced lung diffusion capacity, low exercise capacity, muscle weakness, mental problems and reduced cognitive function resulting in a generally poor health status. Whether these health consequences persist on the long-term is unknown.

Study objective

The overall aim of this study is to assess the multidimensional health status of COVID-19 survivors one year post-infection using validated subjective and objective measures.

Study design

This study will be a single center prospective observational study investigating 200 COVID-19 survivors.

Study burden and risks

Risks and inconveniences associated with this study are minimal and are limited to the time investment of performing the measurements and to possible confronting questions in several questionnaires. Blood drawing is the only invasive procedure to be undertaken during the measurement days, and given the routine status of this procedure, also within our own research group, we expect this procedure to pose no risks to participants. We will measure lung function by spirometry before and after inhalation of salbutamol (bronchodilator). This is a standard procedure to measure the reversibility of the lung function. The inhalation of salbutamol may sometimes be associated with dizziness and palpitations. However, this will resolve shortly after inhalation. There is no risk associated with the DEXA-scan. The radiation dose emitted during a DEXA-scan is 0.001 mSv. This is very low exposure compared to the total background radiation in the Netherlands, which is ±2.5 mSv/year. In addition, we will obtain a chest CT-scan. This chest-CT-scan exposes the subjects to extra radiation (±2-3 mSv), which is still in the range of the yearly total background radiation in the Netherlands. Although this radiation is low, it may put subjects at a slightly increased risk for developing cancer. Moreover, incidental findings might be seen on these scans, such as pulmonary nodules, that need further diagnostic work-up outside the frame of this research. Such

findings may result in additional diagnostic procedures and may lead to unwarranted subject discomfort during such a diagnostic trajectory. Based on these risks, obtaining a chest-CT-scan is voluntary for the subjects. In case subjects do not want a chest CT-scan, they can still participate in the study. In total, subjects have to come one full day or two half days for measurements to the MUMC, depending on the preferences of the subjects.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6202 AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• COVID-19 positive based on:
- Confirmed RT-PCR;
- Proven serology for SARS-COV-2 with clearly associated complaints for a SARS-COV-2 infection;

- CO-RADS score of 4 or more with a proven serology for SARS-CoV-2 afterwards.
• Age of >=18 years;
• Able to provide informed consent;
• Understanding of Dutch language.

Exclusion criteria

• Patients not willing to participate;
• Investigator*s uncertainty about the willingness or ability of the patient to comply with the protocol requirements.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-02-2022
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	16-09-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT04794985
CCMO	NL76949.068.21

Study results

Date completed: 20-08-2024

Summary results
Trial ended prematurely