Neurological and neuropsychological sequelae of Covid-19 infection

Published: 02-11-2020
Last updated: 08-04-2024

To investigate the neurological and neuropsychological sequelae of COVID-19 infection for which ICU or non-ICU hospital admission was necessary in the spring of 2020 and for which ICU admission was necessary in the fall of 2020, and its consequences...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON55029

Source
ToetsingOnline

Brief title
Nenesco

Condition

- Neurological disorders NEC
- Respiratory tract infections

Synonym
corona disease, Covid-19 infection

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: acute respiratory distress syndrome, Covid-19, neurological, neuropsychological

Outcome measures

Primary outcome

Patient-related outcome: participation and quality of life. Caregiver-related outcome: caregiver burden and quality of life. Neurological outcome: MRI abnormalities and neurological symptoms. Neuropsychological outcome: global and domain-specific deficits in cognitive functioning. Emotional outcome: mood and impact of event. Secondary outcomes: subjective complaints in several areas of functioning.

Secondary outcome

not applicable

Study description

Background summary

Severe COVID-19 infection may lead to brain damage, but information is currently lacking because this is a new disease.

Study objective

To investigate the neurological and neuropsychological sequelae of COVID-19 infection for which ICU or non-ICU hospital admission was necessary in the spring of 2020 and for which ICU admission was necessary in the fall of 2020, and its consequences on daily life functioning and quality of life on patients and primary caregivers.

Study design

Multicentre follow-up cohort study with measurements at minimally 6 and 6 months later post discharge from hospital.

Study burden and risks

We foresee no additional risk of measurements. Additional burden consists of one MRI scan and cognitive tests: max 3 hours during the visit at 6-9 months, and twice 30-40 minutes of filling in questionnaires (patients and caregivers) at home at minimalyy 6 months and 6 months later. No potential benefits from participating in this study.

Contacts

Public
Universiteit Maastricht

Universiteitsingel 40
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitsingel 40
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Patients:
- Objectified COVID-19 infection for which ICU or hospital admission was necessary at one of the participating hospitals
- Age > 18 years
- Sufficient command of the Dutch language to follow test instructions and understand questionnaires
- Informed consent.

Primary caregivers (if present):
- Primary caregiver (spouse or close family member who takes care of the patient most) of a participant with COVID-19 infection as described above
- Age > 18 years
- Sufficient command of the Dutch language to understand questionnaires
- Informed consent.

Patients subgroup second/third wave :
- Objectified COVID-19 infection for which ICU or non-ICU hospital admission was necessary at the MUMC+one of the participating hospitals
- Age > 18 years
- Sufficient command of the Dutch language to follow test instructions and understand questionnaires
- Informed consent
- Treated with both dexamethasone and tocilizumab during ICU admission.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

Patients:
- objectified cognitive impairments before the hospital admission for the COVID-19 infection
- an unexpected incident leading to severe neurological damage occurring after hospital discharge (such as stroke or traumatic brain injury)
- contra-indications for MRI scanning (e.g. metal implants, cardiac pacemaker, claustrophobia, pregnancy)
-- physical inability to independently travel to one of the participating hospitals (e.g., bedridden patients).

Primary caregivers: no exclusion criteria.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2021
Enrollment:	430
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-10-2021
Application type:	Amendment
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
CCMO	NL75102.068.20