A prospective cohort study evaluating the occurrence of short and long-term cardiovascular complications in patients hospitalized with COVID-19

Published: 29-03-2021
Last updated: 04-04-2024

To determine the occurrence and natural history of (subclinical) cardiac abnormalities during hospital admission for COVID-19 and the possible cardiovascular complications short-tem (6 months) and long-term (1,2,5,10 years) post-admission.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON52303

Source
ToetsingOnline

Brief title
CAPACITY 2

Condition

- Cardiac disorders, signs and symptoms NEC
- Embolism and thrombosis

Synonym
cardiac abnormalities, cardiac complications

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW,Hartstichting;Euroqol Foundation,Philips

Intervention

Keyword: cardiovascular complications, COVID-19, MACE, SARS-CoV-2

Outcome measures

Primary outcome

To determine the incidence of major adverse cardiovascular events (MACE) on the short (6-months) and long-term (1-, 2-, 5- and 10-years) in patients that have been hospitalized for COVID-19.

Secondary outcome

• The incidence of all-cause mortality on the short (6-months) and long-term (1-, 2-, 5- and 10-years).

• To establish the incidence of systolic and diastolic ventricular dysfunction on echocardiography during hospital admission for COVID-19 and 6-months after admission in patients with and without a clinical indication to receive cardiological care during hospital admission according to the NVVC guideline.

• To determine if echocardiographic abnormalities detected during hospitalization persist or are reversible 6-months post admission.

• To evaluate the efficiency of the healthcare pathway to identify patients with persisting cardiac abnormalities and MACE during follow-up.

• To determine the prognostic value of myocardial injury and echocardiographic abnormalities during hospitalization to predict MACE on the short (6-months) and long-term (1-, 2-, 5- and 10-years).

• To determine how the incidence of MACE in patients hospitalized for COVID-19 relates to the incidence of MACE after hospitalization for seasonal influenza and other common respiratory tract infections.

• To evaluate whether the incidence of (subclinical) cardiovascular complications is related to COVID-19 disease severity.

• To evaluate patients reported outcome measures (PROM*s) up to five years after hospitalization for COVID-19.

• To establish whether PROM*s collected during follow-up predict the occurrence of systolic- and diastolic dysfunction on echocardiography and MACE.

• To determine the impact of myocardial injury and echocardiographic abnormalities during hospitalization on PROM*s on the short (6-months) and long-term (1-, 2-, 5-and 10-year).

• To evaluate the added value of troponin levels and various inflammatory markers measured <24h of admission for the prediction of in-hospital mortality.

• To evaluate the incidence of (subclinical) cardiac arrhythmias using a wearable single lead ECG.

• To evaluate whether findings obtained with the wearable biosensor predict the occurrence of MACE.

• To determine the prevalence, reversibility and prognostic significance of cardiac abnormalities on Cardiac Magnetic Resonance (CMR) scan after SARS-CoV-2 infection

Study description

Background summary

Concerns of cardiovascular complications after a SARS-CoV-2 infection have been raised after a number of case reports and imaging studies performed after a COVID-19 infection. This has fueled media headlines and leads to distress among the public and patients with pre-existing cardiovascular disease. This study wants to perform a prospective study to overcome limitations of existing studies to be able to ascertain a causal relationship between SARS-CoV-2 infection and observed (cardiovascular) findings with a long-term follow-up to assess the occurrence and natural history of cardiac abnormalities.

Study objective

To determine the occurrence and natural history of (subclinical) cardiac abnormalities during hospital admission for COVID-19 and the possible cardiovascular complications short-tem (6 months) and long-term (1,2,5,10 years) post-admission.

Study design

This study is designed as a national prospective cohort study and will be conducted in ~20 larger peripheral and academic hospitals in the Netherlands with an inclusion of ~25 patients per site. A total of 500 patients will be included and receive follow-up.

Study burden and risks

According to the recommended standardized health care pathway that will be implemented, most procedures (medical history, physical examination, hematology, blood chemistry, cardiac biomarkers, ECG, cardiac MRI) will be part of the regular recommended care. Echocardiography (2x), physical examination (1x) and the ECG at 6 month follow-up for the control group and questionnaires for both groups are study examinations.
If a patient participates in the CMR substudy, a CMR scan will be performed 6 months after the initial admission to the hospital with COVID-19 and will be repeated after 9 months and possibly 12 months, depending on the findings of the first CMR scan.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age >=18 and <70 years
• A PCR confirmed infection with SARS-CoV-2 <48h of admission
• Treatment of COVID-19 is the primary reason of hospitalization
• The patient was independent in ADL prior to admission
• The patient or proxy (close relative) is capable of giving informed consent

To be included in the healthcare pathway group, at least two of the following additional criteria should be met within 48h of admission:
• Troponin levels >4x ULN
• New ECG abnormalities including repolarization abnormalities, arrhythmia, signs of right ventricular strain, axis deviation, dynamic ECG changes or any other new abnormalities on ECG deemed clinically relevant by a cardiologist. NOTE: This criterion is not met in case of any (likely) pre-existent electrocardiographic abnormalities.
• Suspicion of cardiac disease

To be included in the control group, at least two of the following criteria should be met within 48h of admission:
•Troponin levels <4x ULN

•No new ECG abnormalities including repolarization abnormalities, arrhythmia, signs of right ventricular strain, axis deviation, dynamic ECG changes or any other abnormalities deemed clinically relevant by a cardiologist).
•No suspicion of cardiac disease

Exclusion criteria

Anticipated) in-hospital stay <48h
• First admission for COVID-19 took place in another hospital and the patient was transferred to the current hospital >48h after first admission
• Recent (<6 months) cardiac pathology prior to hospital admission including:
o Myocardial infarction or unstable angina
o Decompensated heart failure that required hospital admission
o Uncontrolled ventricular arrhythmia
o Percutaneous coronary intervention, CABG, valvular replacement or any other major cardiac surgery
o Cardiac device implantation
o NOTE: Cardiac pathology secondary to a SARS-CoV-2 infection is not a reason for exclusion.
• Anatomical deviations (incl. breast implants) anticipated to significantly hamper the echocardiographic imaging quality
• Clinical signs of severe cerebral dysfunction
• Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol
• (Planned) pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-06-2021
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-05-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-12-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-04-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL76035.041.21