Immunity against SARS-CoV-2 Omicron variant

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

Summary

ID

NL-OMON55169

Source
ToetsingOnline

Brief title
Omicron variant immunity

Condition

- Viral infectious disorders

Synonym
Coronavirus, COVID

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immune response, Omicronvariant, SARS CoV-2, viral load

Outcome measures

Primary outcome

The key objective of the study is to characterize the immune response against

SARS-CoV-2 omicron variant.

Secondary outcome

Secondary objectives:

1. Does the clinical course of disease correlate to viral loads and the immune

response?

2. How is the CT value of the PCR correlated with the viability of the virus ?

3. How is the immune response correlated to viability of the virus?

Study description

Background summary

Two years into the pandemic, continued measures and restrictions remain necessary to control viral circulation and prevent collapse of health care systems. Vaccines were rapidly developed and were shown to be highly effective at preventing severe disease and mortality. Mass immunization programs were rolled out internationally, but vaccine coverage still strongly varies between regions. Among the many factors driving the ongoing circulation of SARS-CoV-2, is the surge of new variants, harboring mutations that favor transmission or that convey an escape from immunity induced by vaccination or previous infection with a different variant.

The SARS-CoV-2 omicron variant was recently described in Southern Africa, associated with a rapid surge in cases, raising international concern about the impact of novel mutations on transmission, disease severity and immunity1. The aim of the current study is to evaluate the immunity against SARS-CoV-2 omicron in vaccinated and unvaccinated individuals.

Study objective

The key objective of the study is to characterize the immune response against SARS-CoV-2 omicron variant.

Secondary objectives:
1. Does the clinical course of disease correlate to viral loads and the immune response?
2. How is the CT value of the PCR correlated with the viability of the virus ?
3. How is the immune response correlated to viability of the virus?

Study design

A prospective study of health care workers with symptoms of COVID.

All participants at day 0:
• Combined nose-throat swab collected in virus transport medium: this is diagnostics and not done for the purpose of the study
• One serum tube
• Request to fill a questionnaire and diary during disease

HCW tested SARS CoV-2 positive :
• Combined nose-throat swab collected in virus transport medium upon recovery
• One serum tube upon recovery
• One serum tube 21 days after the first swab for diagnostics (day 0)

HCW tested SARS CoV-2 negative :
• One serum tube 21 days after the first swab for diagnostics (day 0)

The second phase of the study will focus on immune responses upon vaccination, and efficacy of vaccination in HCW with and without prior infection with SARS CoV-2. For this aim, we will contact a maximum of 200 HCW with a confirmed SARS CoV-2 infection and a maximum of 200 HCW without SARS CoV-2 infection for vaccination follow up. In these HCW we will collect a blood samples prior to their first vaccination, prior to second vaccination, 28 days post vaccination, 6 months and 1 year post vaccination. Following Erasmus MC policy, all HCW will be urged to continue sampling and SARS CoV-2 testing once symptoms occur. In the participating HCW these specimen will be labelled; besides a routine PCR we will perform virus culture and sequencing.

The third phase of the study will focus on the study participants who receive a booster vaccination. In these participants blood will be drawn prior to the boost vaccination, 28 days after the boost and 1 year after the boost. HCW who choose not to get a boost vaccine can continue with study phase 2.

The fourth phase involves parallel study, in which inclusions will be expanded

to non-HCW with confirmed SARS-CoV-2 omicron infection, acquired either during travel or within the Dutch community. The reason to expand the study population was to promote rapid collection of sufficient clinical samples to answer key questions concerning the potential public health threat of this recently identified variant. These results will be analyzed separately.

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Adults > 18 years, with confirmed SARS-CoV-2 omicron infection.

Exclusion criteria

geen

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2020
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-06-2020

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-01-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-11-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-11-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL73601.078.20