Third population-based immune surveillance study used for the evaluation of immunity against SARS-CoV-2

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To assess achieved immunity against COVID-19 across the different age groups in The Netherlands by testing a representative part of the Dutch population for the presence of SARS-Cov-2 specific antibodies in serum

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

Summary

ID

NL-OMON52416

Source
ToetsingOnline

Brief title
Immunity against SARS-CoV-2 in Dutch population (PIENTER Corona)

Condition

- Viral infectious disorders

Synonym
COVID-19, SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: RIVM

Source(s) of monetary or material Support: Ministerie van VWS/het RIVM

Intervention

Keyword: COVID-19, Immunity, SARS-CoV-2, Surveillance

Outcome measures

Primary outcome

To assess achieved immunity against COVID-19 over time across the different age groups in The Netherlands by testing a representative part of the Dutch population for the presence of SARS-Cov-2 specific antibodies in serum

Secondary outcome

To assess the quantity and quality (i.e. antibody functionality and avidity) of the antibodies raised against SARS-CoV-2 in a representative part of the Dutch population, and to identify subgroups (including risk groups) with different levels of immunity against COVID-19

To assess the development of immunity during and after the first pandemic wave and the period thereafter

To assess the existence of cross-reactive antibodies against established coronavirus infections in the past

To asses the antibodies in the mucosal fluid

Study description

Background summary

The first person infected with the novel coronavirus, SARS-CoV-2, that presented with COVID-19 disease, emerged on November 2019 in Wuhan, China. Since then, the virus has spread worldwide, with new cases emerging every day. The first COVID-19 case in the Netherlands was confirmed on February 27, 2020. At this moment, the scope of undetected spread of the virus, the fraction of immune persons due to recent infection, and the course of further spread within the Netherlands is largely unknown. Since, the spreads rapidly, laboratory testing of all suspected cases is not feasible anymore. The sera, collected in the previous PIENTER 3 study, provides an unique opportunity to function as baseline for antibody levels against SARS-CoV-2 of the Dutch population prior to the COVID-19 pandemic. In the present study proposal, PIENTER 3 participants, that had previously indicated that they could be approached for a follow-up study, will be asked to donate a finger prick blood sample by self-sampling and fill in a questionnaire at different time points during and after the coronavirus pandemic in the Netherlands. Additionally, at the start of the second sampling round, we will invite subjects who are more evenly spread over the Netherlands. This follow-up sampling will obtain insight in the obtained humoral immunity against SARS-CoV-2 during this first pandemic wave in the Netherlands. This is important to monitor the status of the generated immunity against SARS-CoV-2 as well as to identify possible gaps among different age groups in The Netherlands, to identify risk groups that are not immune. Furthermore, data from this study can contribute to the evaluation of recently implemented intervention measurements by policy makers and to take decisions for new measurements needed). In addition, it may provide clues how the pandemic will evolve; can we get the pandemic under control, can we stabilize it, or can we expect a new pandemic period?

Study objective

To assess achieved immunity against COVID-19 across the different age groups in The Netherlands by testing a representative part of the Dutch population for the presence of SARS-Cov-2 specific antibodies in serum

Study design

The present study is an observational, longitudinal prospective study in a representative part of the Dutch population (age 1-93 years). A total of approximately 6000 persons will be approached, that previously participated in the PIENTER 3 study (2016/17) and had indicated that they could be approached for a follow-up study. Additionally, at the start of the second sampling moment, we will invite a selection of 27200 persons who are more spread over the Netherlands and also contain 1-2 years olds. Participants will be asked to donate a finger prick blood sample by self-sampling and fill in a questionnaire at different time points during and after the coronavirus pandemic in the

Netherlands. The intention is to collect samples in 8500 participants over a time period of 18 months, with a maximum of 6 different sampling time points, guided by the epidemiology of the pandemic (reporting rates). The first timepoint for sampling will be as soon as possible, thereafter sampling moments will be chosen based on epidemiological information. The study has been elongated to a max of 15 round, and extra participants were invited. As of round 8 a subgroup will collect mucosal fluid.

Study burden and risks

The study is designed to include a representative sample of the Dutch population aged 1-93 years. The main objective can only be investigated in case all age groups are invited.
Blood collection by fingerpick is a standard procedure which is generally accepted. The sensation of a fingerprick can be discomfortable for some participants. The risk of blood collection is considered minimal. The risk of mucosal fluid is considered minimal. There are no personal benefits for the participants of the study. We will inform the participants of their personal test results (if we find antibodies against SARS-CoV-2 in their blood), however with the notice that the results cannot tell if they are protected against SARS-CoV-2, and that we also don't know how long the antibodies will last. By joining this study the participants contribute to the public health related to the current coronavirus pandemic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Subject previously participated in the PIENTER 3 study (2016/17), and had indicated that they could be approached for a follow-up study, or subjects from a random age-stratified sample from the Netherlands

Exclusion criteria

not applicable

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-03-2020

Enrollment:	14000
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-06-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-08-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-09-2021

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-06-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-10-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	10-04-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 21435
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73474.100.20
Other	NL8473

Study results

Date completed:	18-12-2024
Results posted:	23-09-2020
Actual enrolment:	11229

First publication
01-01-1900

URL result
URL
Type
ext
Naam
www.rivm.nl
URL