

# 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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	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 assess 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 uncomfortable 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: NTR

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