Immunity against SARS-CoV-2 in Dutch population

Published: 23-03-2020
Last updated: 15-05-2024

During the pandemic wave the immunity against COVID-19 will build up across the different age groups in The Netherlands.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21435

Source
NTR

Brief title
PIENTER Corona

Health condition

COVID-19, SARS-CoV-2

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM)
Source(s) of monetary or material Support: National Institute for Public Health and the Environment (RIVM), Ministry of Health, Welfare and Sport

Intervention

Outcome measures

Primary outcome

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

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 determine the duration of immunity and the cross-immunity to new variants of SARS-CoV-2 induced by infection and/or vaccination. To study the impact of COVID-19 control measures on immunity to, and infection with, respiratory pathogens that are of epidemiological and clinical concern once they resurge in the Dutch population.

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. 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? Amendment 1: In addition to the previous PIENTER 3 participants, another approximately 13,600 subjects will be invited to obtain seroprevalence data from a larger sample with more municipalities included. This will provide a more complete picture of seroprevalence of COVID-19, especially considering the geographic

clustering of COVID-19 a wider geographic spread is desirable. Furthermore, this allows us to detect minor changes in antibody levels among particular subgroups (1-3%), such as age groups, but also minor changes in time when antibody levels from samples taken at different time points are compared. Furthermore, it enables us to have information from the whole country, including geographically areas that were not sampled in the previous sampling frame. With both groups we estimate to reach an inclusion of ~7000 participants. Amendment 5: follow-up of the trial to a maximum of 15 fingerprick bloods in 5 years. For the follow-up all existing participants can participate, additionally 66.000 new subjects are invited to participate. For more information about the previous study: PIENTER3 study (NL5467 / NTR5611).

Study objective

During the pandemic wave the immunity against COVID-19 will build up across the different age groups in The Netherlands.

Study design

The intention is to collect serum samples and questionnaire data over a time period of 5 years, with a maximum of 15 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.

Intervention

Not applicable

Contacts

Public
RIVM
Alienke Wijmenga-Monsuur

NA
Scientific
RIVM
Alienke Wijmenga-Monsuur

NA

Eligibility criteria

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

There are no exclusion criteria.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-03-2020
Enrollment:	14000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
To be determined

Ethics review

Positive opinion

Date:	23-03-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52416
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8473
CCMO	NL73474.100.20
OMON	NL-OMON52416

Study results

Summary results
https://pubmed.ncbi.nlm.nih.gov/33632374/
https://pubmed.ncbi.nlm.nih.gov/33624751/
https://pubmed.ncbi.nlm.nih.gov/33249407/
https://pubmed.ncbi.nlm.nih.gov/33772265/
https://pubmed.ncbi.nlm.nih.gov/34114187/