Immunity against SARS-CoV-2 in Dutch population

Gepubliceerd: 23-03-2020 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21435

Bron
Nationaal Trial Register

Verkorte titel
PIENTER Corona

Aandoening

COVID-19, SARS-CoV-2

Ondersteuning

Primaire sponsor: National Institute for Public Health and the Environment (RIVM)
Overige ondersteuning: National Institute for Public Health and the Environment (RIVM), Ministry of Health, Welfare and Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

RIVM
Alienke Wijmenga-Monsuur

NA

Wetenschappelijk

RIVM
Alienke Wijmenga-Monsuur

NA

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

There are no exclusion criteria.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-03-2020
Aantal proefpersonen:	14000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
To be determined

Ethische beoordeling

Positief advies

Datum:	23-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52416
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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/