VASCO study (Vaccine Study COvid-19)

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26317

Bron
NTR

Verkorte titel
VASCO

Aandoening

Covid-19

Ondersteuning

Primaire sponsor: Dutch Ministry of Welfare and Sports
Overige ondersteuning: Dutch Ministry of Welfare and Sports

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is time to first symptomatic SARS-CoV-2 infection, determined by a positive PCR or antigen test in combination with COVID-19 related symptoms. Those infections can be detected through the national testing programme.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Several COVID-19 vaccines have been (and will be) registered for use in the general population. COVID-19 vaccination started in the Netherlands in January 2021.Vaccination will sequentially target different groups, starting with specific groups of health care professionals and vulnerable persons. The goal is to vaccinate all adults in the course of 2021. COVID-19 vaccines have shown to be efficacious against COVID-19 in registration trials. These trials were not powered to assess efficacy in subgroups, such as age and risk groups. Also, follow-up to date has been limited to a few months, and the duration of protection is not yet known for any of the licensed vaccines. Furthermore, virus variants have and could emerge that might influence the (duration of) protection. Therefore, postmarketing observational studies are needed to assess vaccine effectiveness (VE) in the real world, to assess differences by vaccine and by age and risk group. This will inform on the future vaccination strategy, i.e. the possible need for revaccinations/booster vaccinations.
Objective: The primary objective is to estimate product-specific vaccine effectiveness (VE) of the COVID-19 vaccines that are used in the Dutch national vaccination program against symptomatic SARS-CoV-2 infection by age and medical risk group at a time point where most participants received vaccination at least 6 months before (i.e. approximately 9 months after start of the study). Secondary objectives include estimating VE by time since vaccination, number of doses and interval between doses, and over longer follow-up time; estimating VE against SARS-CoV-2 infection by severity (asymptomatic, mild, severe); and monitoring of unsolicited adverse events for which medical attention was sought.
Study design: An observational population-based prospective cohort study. This study will use the existing SARS-CoV-2 testing infrastructure and COVID-19 vaccination strategy in the Netherlands. Preferably, participants will be included (as long as possible) before they received a first COVID-19 vaccination. At baseline, participants will be asked to take a self-collected fingerpick sample at home and to complete a baseline questionnaire via app or website. Data collected in the questionnaire includes sociodemographic variables, health status (including underlying conditions and previous SARS-CoV-2 infection), vaccination, and behaviour regarding COVID-19 measures. During follow-up participants will be asked to fill out monthly questionnaires via an app or website including questions about COVID-19 vaccination, testing for SARS-CoV-2 infection, changes in health status and behaviour regarding COVID-19 measures. Participants are asked to notify in the app when they tested positive for SARS-CoV-2 or when they received a COVID-19 vaccination. Also, participants are asked to collect a self-collected fingerpick during follow-up at 6 and 12 months after inclusion in the study. Also 1 month after vaccination, a fingerpick blood sample is taken. Fingerpick blood samples are collected to measure antibodies to detect previous SARS-CoV-2 infections which were not detected by PCR or antigen tests, due to asymptomatic infections or because participants did not get tested. In samples collected after vaccination vaccination response can be measured. Furthermore, information on SARS-CoV-2 testing and COVID-19 vaccination will be obtained through linkage with the national vaccination register and linkage with GGD-registrations where possible. Additional information about health status and hospitalization will be obtained through information from General Practitioners (GPs) and hospitals.

Participants will be followed up for 5 years. Further knowledge or changes in the COVID-19 pandemic might lead to new research questions which cannot be foreseen. Sub-studies embedded into this cohort study will be designed at a later stage, for example in-depth studies investigating immunogenicity requiring more frequent blood sampling or other data collection. Such sub-studies are not described in the current protocol.
Study population: 50,000 participants will be enrolled, divided into three different target groups for COVID-19 vaccination:
1. 30,000 community-dwelling persons aged 60-79 years
2. 10,000 community-dwelling persons aged 18-59 years with a medical indication for being prioritized for COVID-19 vaccination
3. 10,000 community-dwelling persons aged 18-59 years without a medical indication for being prioritized for COVID-19 vaccination.
Participants will be recruited through a random selection from the national population registry (Basis Registratie Personen - BRP), stratified by age (18-39, 40-59 and 60-79 years). To enable enrolment of a sufficient number of participants in target group 2, this group will be oversampled through recruitment via GPs. Participants will also be recruited via (social) media campaigns.
Intervention (if applicable): COVID-19 vaccination will be given as part of the national vaccination program, and is not done by the study team.
Main study parameters/endpoints: The primary endpoint is symptomatic SARS-CoV-2 infection, determined by a positive PCR or antigen test in combination with COVID-19 related symptoms. Secondary endpoints are SARS-CoV-2 infections by disease severity and unsolicited adverse events of special interest following vaccination.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: At baseline and during follow-up participants are asked to complete questionnaires via app or website. In addition, participants will be asked to donate fingerpick blood (maximum of 0.5 ml/sampling timepoint) at baseline, at 6 and 12 months after inclusion in the study, and 1 month after vaccination, which may cause minor discomfort. Overall, the burden for the participants will be small and is justified given the importance of assessing the VE of the different vaccines to inform (future) vaccination policy. There are no personal benefits for the participants of the study, however the participants contribute to public health insights relevant for future control of the COVID-19 pandemic, especially related to the vaccination program.

Doel van het onderzoek

This long-term follow-up real-world study will lead to insights to emerging virus variants as well as provide information on the duration of protection. This study will also provide an infrastructure to conduct sub-studies, for example to assess immunogenicity of different COVID-19 vaccines. In addition, as of now unforeseen situations could occur in the following years which could be studied in this well-defined population cohort of vaccinated and unvaccinated participants.

Onderzoeksopzet

First year: every month; Second to fifth year: every 3 months

Onderzoeksproduct en/of interventie

No intervention

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Community dwelling adult between 18-79 years
- Informed consent provided
- Be able to read, understand and write Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not able or willing to understand and sign the informed consent
- Not able to fill out a digital (app) questionnaire
- Persons living in an institution (e.g. elderly care home, nursing home)

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 nog niet gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	50000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
The collection and processing of personal data from participants enrolled in the study will be limited to those data that are necessary to fulfil the objectives of the study. The data is collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations. Appropriate procedures are implemented to protect the personal data against unauthorized disclosure, access, loss or alteration. Data from the eCRF and the VASCO web portal will be pseudonymized (participants will be assigned a unique identification number in Your Research platform) and stored in a study database (Your Research platform). Only authorised study staff will be allowed to enter data into the eCRF and make changes to eCRF data. These data will lack any personal identifiers.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55915
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9279
CCMO	NL76815.056.21
OMON	NL-OMON55915

Resultaten