VASCO study: A population-based prospective cohort study on vaccine effectiveness of COVID-19 vaccines in the Netherlands

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

Summary

ID

NL-OMON55915

Source
ToetsingOnline

Brief title
VASCO study

Condition

- Viral infectious disorders

Synonym
corona, COVID-19, SARS-CoV-2 infection

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Volksgezondheid, Welzijn en Sport (VWS)

Source(s) of monetary or material Support: Ministerie van Volksgezondheid;Welzijn en Sport

Intervention

Keyword: COVID-19, Effectiveness, Vaccine

Outcome measures

Primary outcome

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 outcome

Secondary endpoints are SARS-CoV-2 infections by disease severity and

unsolicited adverse events of special interest following vaccination.

Study description

Background summary

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 always 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, post-marketing observational studies are needed to assess vaccine effectiveness (VE) in the real world and 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.

Study 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 (quaterly after the first year) 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 every 6 months after inclusion in the study. Also 1 month after primary 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. In a subset of participants who report a positive SARS-CoV-2 test, after being fully vaccinated, we will ask them to donate an additional fingerpick blood sample to measure serum SARS-CoV-2 specific antibody concentrations and antibody avidity. 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. From April 2022 onwards, participants will receive SARS-CoV-2 self-tests to be used when having symptoms in order to keep track of SARS-CoV-2 infections. From June 2023, participants are asked to send in positive self-tests for sequencing to determine the variant causing the infection.

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. The first sub-study includes the invitation of participants to donate an extra fingerpick blood sample after testing SARS-CoV-2 positive after being fully vaccinated (breakthrough infection).

Study burden and risks

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 and every 6 months during follow-up, and for some participants,1 month after primary vaccination, and after a breakthrough infection, 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Community dwelling adult between 18-84 years
- Informed consent provided
- Be able to read, understand and write Dutch

Exclusion criteria

- 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)

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-05-2021
Enrollment:	50000
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	12-03-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-11-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-05-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-12-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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: 26317
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76815.056.21
OMON	NL-OMON26317