Immune responses Induced by Vaccination Against COVID-19 in Dutch healthy subjects

Published: 20-04-2021
Last updated: 14-03-2025

Monitoring & evaluation of immune responses induced by COVID-19 vaccines in the general population in the Netherlands.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51214

Source
ToetsingOnline

Brief title
IIVAC

Condition

- Other condition
- Viral infectious disorders

Synonym
corona, prevention

Health condition

immuunsysteem

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Volksgezondheid, Welzijn en Sport (VWS)
Source(s) of monetary or material Support: Ministerie VWS/het RIVM

Intervention

Keyword: Corona, COVID-19, Immune response, Vaccination

Outcome measures

Primary outcome

The primary parameter of the study is COVID-19 vaccine (e.g. Spike protein)-specific serum IgG (GMC) at day 28 after completion of COVID-19 vaccination, by multiplex immune assay (MIA).

Secondary outcome

a. Humoral, cellular and innate COVID-19 vaccine-induced immune responses

b. Virus neutralizing capacity of antibodies induced by COVID-19 vaccination

c. Fc functionality of antibodies (e.g. complement deposition) and antibody glycosylation status induced by COVID-19 vaccination

d. COVID-19 vaccine-induced antibodies in nasal mucosal lining fluid

e. Reactogenicity self-reported in questionnaires shortly after vaccination

Study description

Background summary

Vaccination against SARS-CoV-2 is the most effective way to end the current pandemic. However, it is currently unknown which level and type of immune responses will be induced by COVID-19 vaccination in the Dutch general population. This study aims to evaluate humoral, cellular and innate immune responses induced by COVID-19 vaccines in generally healthy subjects in the Netherlands. This includes neutralizing antibodies, associated with prevention of infection by SARS-CoV-2, as well as other immune parameters that may govern

vaccine-induced protection against disease and transmission. Also, the study will provide a comparison of immune responses in these healthy subjects with responses in risk groups that are being assessed in other trials. Ultimately, the study supports evidence-based vaccination strategies to reach and sustain optimal population immunity.

Study objective

Monitoring & evaluation of immune responses induced by COVID-19 vaccines in the general population in the Netherlands.

Study design

Longitudinal observational study.

Study burden and risks

The burden associated with participation involves collection of finger prick blood samples by self-sampling at home for all participants (5 times max. 800 ul per finger prick). In a subset of participants, 3 of 5 finger pricks are replaced by venapuncture blood collections (4 times; 32-89 mL per visit with a max. total volume of 269 mL over 1 year), faeces collection (once) and nasal mucosal lining fluid collection by nasosorption strips (3 times) during the follow up of 1 year. In addition, all subjects will be asked to fill in questionnaires at almost all timepoints. All participants will receive COVID-19 vaccination as part of the national immunization program provided by the Dutch government, that they would have received regardless of this study. The potential risks of sampling performed within the proposed study are considered minimal. The benefit for the individual subjects in this trial is low. Results of the study will support evidence-based optimisation of vaccination strategies within the Dutch population. The amount of collected blood is lower in children and age dependent.

In case of partcipation in the booster vaccination study additional blood will be collected in up to four visits, with an additional max. total volume of 133 ml over 1 year in the subgroup; as well as
additional mucosal lining fluid collection by nasosorption strips at maximal 3 timepoints.
Participants in the general study are asked to perform a fingerpick by which an additional ammount of 3.2 ml blood will be collected (4 timepoints in 1 year, 800 ul each time).
The amount of collected blood is lower in children and age dependent.
All participants are asked to complete a questionairre at timepoints B0-B3.

Contacts

Public
Ministerie van Volksgezondheid, Welzijn en Sport (VWS)

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL
Scientific
Ministerie van Volksgezondheid, Welzijn en Sport (VWS)

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL

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)
Babies and toddlers (28 days-23 months)

Inclusion criteria

- Be 0 - 60 years at the time of inclusion
- Be capacitated mentally and physically
- Be willing to receive SARS-CoV-2 vaccine
- Having signed the Informed Consent

Exclusion criteria

- Participation in a phase I/II/III vaccination trial where the subject will be

vaccinated with a pre-registration (COVID-19) vaccine
• Participation in a phase I/II/III medicine (pre-registration) trial
• Belonging to a risk group for COVID-19 that is studied in one of the ZonMw-funded risk group vaccination studies (details of risk group studies provided in ref.) that this study provides a comparison for:
o Primary (inherited) immune deficiency (VACOPID study)
o Severely decreased kidney function (defined as Chronic Kidney Disease stage 4 or 5 (eGFR<30)), treatment by dialysis or recipient of a kidney transplant (RECOVAC study)
o Pulmonary disease for which the patient will receive or has received a lung transplant (COVALENT study)
o Autoimmune disease (e.g. MS, rheumatoid arthritis, IBD, SLE etc) (Target to B! (sub)study)
o Down syndrome (PRIDE study)
o (Known) infection with Human Immunodeficiency Virus (HIV) (COVIH study)
o Cancer patients and patients with active cancer treatment (including hormone therapy), receipt of chemotherapy in the last 3 years and/or any history of cancer immune therapy (VOICE study)
o Haematological patients, such as haematological malignancies (leukemia and lymphomas), myelodysplastic and -proliferative syndromes, hemoglobinopathies (sickle cell disease and thalassemia), receipt of stem cell transplantation or cell therapy such as CAR T-cell therapy (COBRA-KAI study)
• Any other immune deficiency through disease
• Active or past immunosuppressive or immune modulating medication. However, for steroid treatment the exclusion criteria are: receipt of any high-dose (>= 20 mg of prednisone daily or equivalent) steroid treatment; daily corticosteroids (locally, incl. inhaled steroids, are acceptable) within 2 weeks of study entry; or repeated use of any high dose of corticosteroids (a dose of > 30 mg of prednisone or equivalent per day for multiple days) in the recent past.
• Women who are pregnant or breastfeeding
• Having a (functional) asplenia
• Receipt of blood products or immunoglobulin, within 3 months of study entry
• Receipt of an organ transplant not mentioned above
• For the subgroup: Known or suspected coagulation disorder, also by treatment, that would contraindicate undergoing frequent blood sampling

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-05-2021
Enrollment:	2100
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-05-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-05-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-06-2021
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	01-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-11-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-11-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-08-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-09-2022
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	13-10-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-10-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
Other	2021-001357-31
EudraCT	EUCTR2021-001357-31-NL
CCMO	NL76440.041.21

Study results

Date completed:	12-02-2024
Results posted:	23-04-2024
Actual enrolment:	1459

First publication
01-01-1900

URL result

URL
Type
ext
Naam
www.rivm.nl
URL
Type
ext
Naam
www.rivm.nl
URL