SARS-CoV-2 vaccination response in people living with HIV

Gepubliceerd: 20-01-2021 Laatst bijgewerkt: 19-03-2025

We calculated the sample size on the assumption that the antibody response in HIV positive patients (p) is 90% and the response in HIV negative historical controls of (p0) is 95%, for the SARS-CoV-2 vaccines that are approved at this point in the...

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

Samenvatting

ID

NL-OMON26993

Bron
Nationaal Trial Register

Verkorte titel
COVIH

Aandoening

COVID-19, HIV

Ondersteuning

Primaire sponsor: OLVG, LUMC, Erasmus MC
Overige ondersteuning: in progress

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the humoral vaccine efficacy against SARS-CoV-2 in PLWHIV 2 weeks after the completed vaccination schedule (all participants)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The immune response in people living with HIV (PLWHIV) to any of the SARS-CoV-2 vaccines that are to be implemented for use in the Netherlands used is currently unknown. As observed with other vaccines, this immune response could be hampered by the immune status of PLWHIV.
Objective: To assess the immune response and the reactogenicity to SARS-CoV-2 vaccines in people living with HIV in the Netherlands.
Study design: Observational study (the vaccination is performed by the family doctor or at the municipal health center)
Study population: People living with HIV (in care in one of the 20 participating centers) who will receive a SARS-CoV2 vaccination in 2021
Sample size: we aim to include minimally 550 participants per vaccine, and are planning to target women and older patients
Intervention: An extra blood sample before and 2 weeks after the last SARS-CoV-2 vaccination (maximally 2 blood samples in total, main study). A standardized adverse event dairy post-vaccination.
Main study parameters/endpoints: Proportion of all participants with a protective antibody response to SARS-CoV-2 vaccine overall and according to CD4 nadir

Doel van het onderzoek

We calculated the sample size on the assumption that the antibody response in HIV positive patients (p) is 90% and the response in HIV negative historical controls of (p0) is 95%, for the SARS-CoV-2 vaccines that are approved at this point in the Netherlands

Onderzoeksopzet

1st blood sampling 1-3 weeks before vaccination, subgroup: before second vaccination, 2nd blood sampling 7-21 days after second vaccination, long term response: follow up at regular outpatient monitoring every 6 months until 12 months after vaccination

Onderzoeksproduct en/of interventie

Blood sampling before the first and after the second SARS-CoV-2 vaccination (vaccinations are performed by the family doctor of municipal health center)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

18 years or older, confirmed HIV-infection, selected by national regulations for SARS-CoV-2 vaccination

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

none

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:	20-01-2021
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
We are willing to share our data with restricted access and after an embargo period, details will follow at a later time point

Ethische beoordeling

Positief advies

Datum:	20-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52193
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9214
CCMO	NL76562.100.21
OMON	NL-OMON52193

Resultaten