Healthy volunteers blood sampling

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To screen the immune repertoire of healthy volunteers for broadly reactive antibodies directed against coronavirus S protein, including SARS-CoV-2 and (if found) to isolate/clone and further characterize such antibodies with the ultimate goal of...

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

Samenvatting

ID

NL-OMON25763

Bron
Nationaal Trial Register

Verkorte titel
CHDR2044

Aandoening

SARS-CoV-2, COVID-19, Corona

Ondersteuning

Primaire sponsor: Leyden Laboratories B.V.
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• B-cell response as assessed by enzyme-linked immunosorbent assay (ELISA) and/or enzyme-linked immunosorbent spot assay (ELISpot) and/or flow cytometry methods
• Serology: peptide library scanning

Toelichting onderzoek

Achtergrond van het onderzoek

Two processes are key to infection by any virus: attachment and entry. Viral attachment is achieved through binding of a protein on the surface of the viral particle to a specific receptor (i.e. protein or glycan structure) on the surface of a host cell, whereas entry is defined as the release of the viral proteins and genetic material in the cytosol of the host cell.
In the case of enveloped viruses, attachment and entry are mediated through distinct domains of a single surface protein. Typically, a globular “head” region of this protein contains the Receptor Binding Domain (RBD) while a membrane-proximal “stem” region contains the machinery that mediates viral entry by triggering fusion of the viral and host cell membranes, the so called “fusion domain”.
For Coronaviruses, attachment and entry are mediated by the “Spike” (S) protein. The S1 subunit contains the variable RBD while the S2 subunit contains the fusion machinery.
In order to find human monoclonal antibodies with broad neutralizing activity, the current research will be focusing on interrogating the B-cell repertoire of healthy human donors for antibodies directed against the S domains of the coronavirus S protein using state-of-the-art technology such as flow cytometry.
If broadly neutralizing antibodies are identified using the above-mentioned techniques, Leyden Labs will develop mAb-based inhibition product(s) for prevention of infection and respiratory disease by members of the corona virus family, including SARS-CoV-2.

Doel van het onderzoek

To screen the immune repertoire of healthy volunteers for broadly reactive antibodies directed against coronavirus
S protein, including SARS-CoV-2 and (if found) to isolate/clone and further characterize such antibodies with the ultimate goal of developing an antibody for prophylactic and/or therapeutic use against coronavirus infections.

Onderzoeksopzet

Baseline - EOS

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Participant must sign the study informed consent form prior to any study-mandated procedure indicating that he or she understands the purpose, procedures and potential risks, and is willing to participate in the study;
2. Participant is male or female and between 40 and 65 years of age, inclusive, at the time of enrollment;
3. Participant is willing and able to complete the study procedures;
4. Participant has a primary care physician at the time of enrollment;
5. Participant is generally healthy in the investigator’s clinical judgment, as determined by medical history evaluation, including no clinically significant disorder, condition, infection or disease that would interfere with the study evaluation, procedures or completion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Participant has current clinical symptoms of COVID-19 (including, but not limited to: cough, fever, shortness of breath, sudden onset of anosmia, ageusia or dysgeusia). Note that a participant who reports a previous positive diagnostic test result for SARS-CoV-2 infection (serological testing or viral RNA detection by PCR testing) and who is recovered from COVID-19 for at least three weeks prior to blood sampling is allowed to participate in the study as deemed by the investigator;
2. Participant had recent close contact with a SARS-CoV-2 infected person or someone in their household tested positive for SARS-CoV-2, has travelled to a country/area that has been designated as a COVID-19 risk area according to the effective policies/guidelines of the

National Institute for Public Health and the Environment (Dutch: RIVM) or otherwise meet criteria for home isolation;
3. Participant received immunosuppressive medication or other immunomodulating agents (including investigational drugs) in the 3 weeks prior to study blood sampling or received immunoglobulins or blood products in the 3 months prior to study blood sampling;
4. Participant with a whole blood donation or loss of >500 ml within 21 days before study blood sampling;
5. Any known factor, condition, or disease that might interfere with compliance, study conduct or interpretation of the results, as deemed by the investigator.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-11-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	12-11-2020

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49952
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9045
CCMO	NL75505.058.20
OMON	NL-OMON49952

Resultaten

Samenvatting resultaten
N.A.