A proteogenomic pipeline for capture and sequencing and production of pathogen-specific antibodies

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

Summary

ID

NL-OMON50850

Source
ToetsingOnline

Brief title
Pathobody2020

Condition

- Viral infectious disorders

Synonym
Corona, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: AbSano B.V.
Source(s) of monetary or material Support: Europese Unie en AbSano

Intervention

Keyword: Antibody, Cross-reactive MERS, Cross-reactive SARS, Neutralizing

Outcome measures

Primary outcome

1. Generate human antibodies with high affinity for SARS-CoV-2, which are neutralizing and cross-reactive against older SARS-Cov viruses, and that target a broad spectrum of epitopes, spread across the viral proteome. Antibodies should preferentially enhance each other's efficacy with regard to virus neutralization. Potent antibodies will be either developed into a product, or offered for licensing to a pharmaceutical party that will continue the path towards the market.

2. Establish a set of IP-protected protocols and procedures as a workflow that rapidly yields monoclonal antibody molecules in response to emerging pathogens.

Secondary outcome

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Study description

Background summary

It is known that in patients who are infected with the corona virus, antibodies arise that can stop the virus infection or can reduce the virus infection significantly. By producing these antibodies at large scale, and applying them to people who are recently infected, we can fight the virus efficiently.

Study objective

In this research study we will look whether in the blood of patients who were recently infected with the coronavirus (SARS-CoV-2), antibodies can be found that neutralise the virus. We will produce those antibodies. With the produced

antibodies we will make a medicine that will eliminate or strongly reduce the effect of the virus on patients.

Study design

- Bloodsampling. The researcher takes each time max 6 tubes of blood max 50 ml.
- Antibody characterisation. We will analyse which antibodies against SARS-CoV-2 are in your blood.
- Isolation of B cells. If you have the proper antibodies against SARS-CoV-2 in your blood we will isolate RNA from the B-cells in your blood. B cells are those cells that produce antibodies. We will use the RNA to determine the exact composition of the antibodies so they can be produced.
- Isolate antibodies from the plasma. We will try to directly isolate a small quantity of antibodies from your blood. We will determine the composition of those antibodies with Mass-spectrometry. The is a modern technique to analyse proteins. This will be done so these antibodies can also be produced.

Study burden and risks

The risks associated with venipuncture by a trained professional are negligible. Phlebotomists that will assist in this study are qualified professionals assigned by lnnatoss. Risks associated with drawing blood include pain, bruising, light-headedness, and, on extremely rare occasions, infection. The burden of participation will be limited. Each visit will last up to approximately 15 minutes. There will be no other procedures or follow-up required after the specimens are obtained.

Contacts

Public
AbSano B.V.

Kloosterstraat 9, RE21
Oss 5349 AB
NL
Scientific
AbSano B.V.

Kloosterstraat 9, RE21
Oss 5349 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Over 18 years of age
- Positive PCR in the previous 2 months and/or
- Vaccinated against SARS-CoV-2
- Devoid of symptoms associated with an active SARS-CoV-2 infection

Exclusion criteria

- Individuals who cannot or are not willing to consent.
- Individuals who are undergoing an immunosuppressive treatment.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2021

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	04-06-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-09-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL76229.028.21