Discovery of auto-antibodies in Long-COVID

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Primary Objective: Identifying the auto-antigens that cause long-COVID symptoms Secondary Objective(s): Isolate and sequence the auto-reactive B cells to produce recombinant long-COVID autoantibodies

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

Summary

ID

NL-OMON53317

Source
ToetsingOnline

Brief title
Discovery of auto-antibodies in Long-COVID

Condition

- Other condition

Synonym
long-covid, PASC

Health condition

Post-infectioeuze ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: auto-immunity, Long-covid, PASC

Outcome measures

Primary outcome

Outcome parameters for autoantibody analysis by HuProt will be the presence of

autoantibodies that are unique for the long-COVID patients in venous blood

Secondary outcome

The binding of the recombinant antibodies to the antigens that we identified by

HuProt analysis

Study description

Background summary

About 10-30% of COVID*19 survivors develop long*COVID, indicating a substantial and long-lasting personal and societal impact of this disease at a worldwide level. In our preliminary work, we have identified autoimmunity as a cause of long-COVID.
Yet, it remains unknown whether the induced auto-antibodies are innocent bystanders, or whether they really cause (or amplify) long-COVID symptoms. In order to validate the earlier found auto-antigens and to isolate the responsible B cells to recombinant produce the disease-causing IgG autoantibodies, subsequent longitudinal measurements needs to be analyzed.

Study objective

Primary Objective: Identifying the auto-antigens that cause long-COVID symptoms
Secondary Objective(s): Isolate and sequence the auto-reactive B cells to produce recombinant long-COVID autoantibodies

Study design

This study will obtain venous blood at one single time point. The estimated time of a visit will be approximately one hour. For this study all 34 Long Covid patients will be contacted again to confirm and validate earlier found possible auto-antigens, which could be the cause of Long COVID. With this validation sample it will be possible to predict more accurately which auto-antibodies are responsible for the Long Covid symptoms. The minimal time between the initial blood draw and the still to be performed second blood draw will be three months.

All Long-Covid patients have an informed consent to be contacted for future research throughout the Amsterdam UMC post-COVID-19 biobank. Many of the Long-Covid patients from the outpatient clinic have shown great interest in additional research and therefore we expect no problem to recruit all participants

3.2 Inclusion criteria
In order to be eligible to participate in this study, a Long-Covid patient must meet all of the following criteria:
* Non-hospitalized individuals with prior confirmed diagnosis of severe acute respiratory coronavirus 2 (SARS-CoV-2) infection by reverse transcription-polymerase chain reaction testing or serology (wantai) testing
* No Long-Covid symptoms present before confirmed diagnosis of SARS-CoV-2
* Individuals with diagnosed PASC by an Amsterdam UMC post-covid physician
* Aged between 18-65 years
3.3 Exclusion criteria
* Pregnancy
* Chronic illness

Study burden and risks

Low risk

Contacts

Public
Amsterdam UMC

Meibergdreef 9
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NL
Scientific
Amsterdam UMC

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* Non-hospitalized individuals with prior confirmed diagnosis of severe acute respiratory coronavirus 2 (SARS-CoV-2) infection by reverse transcription-polymerase chain reaction testing or serology (wantai) testing
* No Long-Covid symptoms present before confirmed diagnosis of SARS-CoV-2
* Individuals with diagnosed PASC by an Amsterdam UMC post-covid physician
* Aged between 18-65 years

Exclusion criteria

* Pregnancy
* Chronic illness (including orthopaedic, endocrinological, haematological, malignant, gastrointestinal, neurological, muscle or inflammatory disorders) likely to significantly impact on exercise performance

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2023
Enrollment:	34
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-04-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL83733.018.23

Study results

Date completed:	14-06-2023

Actual enrolment: 32

Summary results
Trial is onging in other countries