The immune biological basis of severe fatigue after COVID-19 infection (IMMUNOFATIGUE)

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To test the hypotheses that patients who show severe fatigue after COVID-19 infection exhibit an exaggerated abnormal expression of inflammatory monocyte genes (particularly of the genes involved in pyroptosis, such as IL-1 and IL-6) as compared to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON56832

Source
ToetsingOnline

Brief title
A biological basis of post-COVID-19 fatigue

Condition

- Immune disorders NEC
- Respiratory tract infections

Synonym
COVID-19, severe fatigue

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COVID-19, Fatigue, Immune system

Outcome measures

Primary outcome

Gene expression profiles and inflammaging in monocytes of fatigued versus

non-fatigued post-COVID patients

Secondary outcome

In fatigued versus non-fatigued post-COVID-19 patients

Cellular immune parameters

- Extensive immunophenotyping of monocyte maturation subsets

- Extensive immunophenotyping of T-lymphocyte maturation subsets, including

recently thymic emigrants

- SARS-CoV2-specific CD8+ T-cell responses using immunodominant SARS-CoV-2

peptides

Molecular parameters

Next generation sequencing of the T-cell receptor repertoire

Study description

Background summary

A large proportion of patients suffer from considerable fatigue in the aftermath of COVID-19 infection.
Recent research in immuno-psychiatry indicates that such fatigue is associated with (and probably partially caused by) a premature senescent state of the immune system. This state is characterized by various T cell defects (low output of naive T cells from the thymus, high levels of terminally

differentiated and exhausted T cells) and by *inflammaging* (high expression of inflammatory genes in monocytes, high levels of pro-inflammatory cytokines in the circulation). It is likely that the COVID-19 infection induces such premature immune-senescent state with chronic low grade inflammation in vulnerable individuals.

Study objective

To test the hypotheses that patients who show severe fatigue after COVID-19 infection exhibit an exaggerated abnormal expression of inflammatory monocyte genes (particularly of the genes involved in pyroptosis, such as IL-1 and IL-6) as compared to unaffected post-Covid-19 patients.

Study design

A: comparative, non-randomized, observational, study
B: Observational cohort

For this study extra Na-Heparin blood (30-35 ml) will be obtained from patients at 3 and 6 months after discharge at the post-COVID outpatient department, and from adult healthy controls. Heparin blood will be used for different types of cellular and molecular analysis.

Study burden and risks

Participants do not benefit, risks are negligible, burden is low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Post COVID-19 diagnosis (based on positive PCR or multidisciplinary team decision based on symptoms and CT or positive serology)
• Referred for outpatient follow-up
• Age >= 18 years
• Provided written informed consent

Exclusion criteria

• Unable or not willing to provide written informed consent
• Unable to complete written questionnaires in Dutch
• Living in a nursing home because of a diagnosis of dementia
• Patients that visit the outpatient clinic in another hospital outside of the region

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	105
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-01-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL75781.078.20