Identifying risk factors in the immune profile of patients with a SARS-CoV-2 infection

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Primary objective: To investigate the baseline systemic immune profile in COVID-19 patients using mRNA expression profiling, and to connect that to clinical outcome in order to identify prognostic and predictive markers that can help in decision...

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

Summary

ID

NL-OMON49107

Source
ToetsingOnline

Brief title
Immune monitoring in COVID-19 patients

Condition

- Viral infectious disorders

Synonym
Coronavirus infection, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO

Intervention

Keyword: COVID-19, Immune monitoring, SARS-CoV-2

Outcome measures

Primary outcome

To investigate the baseline systemic immune profile in COVID-19 patients using mRNA expression profiling, and to connect that to clinical outcome in order to identify prognostic and predictive markers that can help in decision making for individual patients.

Secondary outcome

* To investigate the individual systemic immune profile changes in COVID-19 patients using mRNA expression profiling, and to connect that to clinical outcome.

* To scrutinize the pathogenesis of COVID-19 by connecting the circulating immune profile to that infiltrated in the lung samples of deceased patients.

Study description

Background summary

Currently it is not clear which patients who are admitted to the hospital with a SARS-CoV-2 infection will benefit from treatment at either the general COVID ward or the Intensive Care unit. Based on clinical features, pathology and the pathogenesis of acute respiratory disorder it is suggested that the excessive inflammation, oxidation, and an exaggerated immune response may very likely contribute to COVID-19 pathology. This leads to a cytokine storm and subsequent progression to acute lung injury, diffuse lung embolism and sometimes to death. In early stages of Coronavirus infection, dendritic cells and epithelial cells are activated and express a cluster of pro-inflammatory cytokines and chemokines including IL-1*, IL-2, IL-6, IL-8, both IFN-*/*, and many other secreted molecules that are under the control of the immune system. However, the balanced immune system, including the innate immunity is severely disturbed

in some the SARS-CoV-2 infected patients which contributes to the progression in disease. We believe that monitoring the immunological changes (cell type ratios, cytokines and chemokines) induced by the SARS-CoV-2 virus will lead to discovering prognostic or predictive markers that may assist in decision making and hopefully offers new treatment options.

Study objective

Primary objective: To investigate the baseline systemic immune profile in COVID-19 patients using mRNA expression profiling, and to connect that to clinical outcome in order to identify prognostic and predictive markers that can help in decision making for individual patients. Secondary objectives: 1) To investigate the individual systemic immune profile changes in COVID-19 patients using mRNA expression profiling, and to connect that to clinical outcome. 2) To scrutinize the pathogenesis of COVID-19 by connecting the circulating immune profile to that infiltrated in the lung samples of deceased patients.

Study design

Case control study.

Study burden and risks

For the participating patients there is no direct benefit. However, if we are able to determine an immune profile which can predict clinical outcome this will benefit future patients during their treatment course. Unnecessary Intensive Care treatment can be avoided in elderly patients if the profile predicts a negative outcome. The extra burden consists of a maximum of 3 extra blood collections, however these collections will take place during a standard blood collection or from a permanent peripheral vein catheter.

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

* Age 18 years and older;
* Proven SARS-CoV-2 infection;
* Patient will be admitted to either the general COVID ward or the Internsive Care unit;
* Written informed consent.

Exclusion criteria

* Unable to provide written informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-05-2020
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	04-05-2020
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	NL73767.078.20