Predictive Value of the Angiotensin-II type 1 and Endothelin Receptor Autoantibodies on disease course in COVID-19

Published: 14-01-2021
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To assess the potential of AT1R and ETAR antibodies to serve as a biomarkers for clinical deterioration in COVID-19.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract infections
Study type	Observational invasive

Summary

ID

NL-OMON49663

Source
ToetsingOnline

Brief title
AERA-COVID

Condition

- Respiratory tract infections

Synonym
coronavirus, COVID-19, pneumonia

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: Antibodies, COVID-19, Hypoxemia, Intensive Care, Prediction, Respiratory distress

Outcome measures

Primary outcome

The proportion of patients with an unfavourable outcome in COVID-19.

Secondary outcome

To assess the presence of ANA antibodies in the study patients, and correlate

their presence with ETAR and AT1R antibodies.

To assess the presence and titre of AT1R and ETAR antibodies at admission and

on the seventh day of admission for COVID-19

To assess cFN-EDA levels in COVID-19 patients at admission and on the seventh

day of admission for COVID-19.

Study description

Background summary

A significant proportion of COVID-19 patients admitted to hospital experience clinical deterioration and require ICU admission. In a recently performed cross-sectional study, it was observed that presence of AT1R and/or ETAR antibodies are associated with an unfavourable outcome (defined as requirement of high-flow nasal cannula, ICU admission or death during admission) in COVID-19.

Study objective

To assess the potential of AT1R and ETAR antibodies to serve as a biomarkers for clinical deterioration in COVID-19.

Study design

Prospective single centre, observational cohort study.

Study burden and risks

Peripheral blood will be withdrawn once, after informed consent, by means of vena puncture during admission for COVID-19. Vena puncture can cause mild discomfort; the puncture could be experienced as being painful, and a hematoma could result from this procedure. There are no further risks associated with participation. The subject will not have direct benefit from the findings in this study, but it could be of great value for optimizing risk assessment in the current COVID-19 pandemic.

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

All patients presenting at the Emergency department with respiratory symptoms and/or fever are evaluated for participation.

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age >= 18 years
- Hospitalized with PCR confirmed COVID-19
- Able to sign informed-consent form

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- the patients gives no informed consent
- Already hospitalized for >72 hours

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):	18-11-2020
Enrollment:	320
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-01-2021
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	NL75731.078.20