Biomarker-based Early Anti-inflammatory Therapy for severe COVID-19

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Identifying the pro-inflammatory biomarker profile in the pathophysiology of acute sever lung disease in SARS-CoV-2 infection, and using this profile to identify the patients who are at risk of developing acute severe lung disease and multi-organ...

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

Summary

ID

NL-OMON55200

Source
ToetsingOnline

Brief title
BEAT-COVID-1

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
Coronavirus infection, COVID-19

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biomarkers, COVID-19, Immunity, SARS-CoV-2

Outcome measures

Primary outcome

The main endpoint is the identification of pro-inflammatory biomarkers in the

development of acute severe lung injury and multi-organ failure in infection

with SARS-CoV-2

Secondary outcome

See protocol section 8.1.2 Secondary study parameters/endpoints

Study description

Background summary

The clinical risk factors that predispose to the development of acute severe lung injury in COVID-19 are higher age, obesity, diabetes mellitus and a medical history of heart or lung disease. Besides these known factors, the underlying mechanisms that lead to increased inflammation that appears to be the mechanism of acute severe lung disease and multi-organ failure, remain largely unknown. The inflammatory cytokine IL-6 is increased in patients, and several clinical trials have now been registered which plan to investigate the effect of the anti-IL-6 monoclonal antibody tocilizumab, as an inhibitor of inflammation in COVID-19.
According to the observations of the Chinese patients in Wuhan and other epicentres of the pandemic, and confirmed by our own observations, progression towards severe lung injury and multi-organ failure occurs around one week after onset of symptoms. Beside the known risk factors that somewhat help clinicians predict which patients are vulnerable, in this study, pro-inflammatory biomarker profiles, including IL-6, will be used to stratify these patients in a more substantiated manner. The specific biomarker profiles which are associated with the development of acute severe lung disease, can be targeted in new and patient specific treatments for COVID-19, to prevent further deterioration.

Study objective

Identifying the pro-inflammatory biomarker profile in the pathophysiology of acute sever lung disease in SARS-CoV-2 infection, and using this profile to identify the patients who are at risk of developing acute severe lung disease and multi-organ failure.

Study design

Prospective Observational Cohort Study

Study burden and risks

The burden of this study for the participants is related to extra blood samples and nasal swabs. Therefore, we assume the risk to be negligible and the burden minimal. The study is group related as we only plan to investigate the population with COVID-19 admitted to the hospital.

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

hospitalized patients
- Hospitalized patient with PCR confirmed COVID-19 infection
- Eighteen years or older
healthy volunteers
- Not-hospitalized
- Sixty years or older
- Sars-CoV-2 serology negative
mild infection
- Positive SARS-CoV-2 PCR test from the GGD
- No or limited symptoms of a viral airway infection (fever, cough, dyspnea, rhinorroea, myalgia, anosmia) at the time of inclusion
- Age 18 years or older

Exclusion criteria

Patients and healthy controls
- Not able to give consent by the healthy volunteer, or the patient or patients representative

Healthy controls
- Symptoms of viral airway infection (e.g. fever, cough, rhinorroea, dyspnea) at screening or inclusion

Group of infected individuals with little or no symptoms:
- Having received vaccination against SARS-CoV-2 or previous confirmed infection with SARS-CoV-2.
- Not being able to come to LUMC by own transportation to donate samples.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2020
Enrollment:	275
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-05-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-06-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-06-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	18-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	23-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL73740.058.20

Study results

Summary results
Trial ended prematurely