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

Gepubliceerd: 07-05-2020 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23631

Bron
Nationaal Trial Register

Verkorte titel
BEAT-COVID1

Aandoening

coronavirus; COVID-19

Ondersteuning

Primaire sponsor: Prof. Dr. L.G. Visser
Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Biomarker profiles or signature which correlate with future clinical progression of patients infected with SARS-CoV-2 to multi-organ failure and acute severe lung injury requiring mechanical ventilation.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
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 [1]. 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.

Objectives:
- 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.
- Identifying cellular immune biomarkers that predict higher chance to develop acute severe lung disease in SARS-CoV-2 infection, both at admission and during monitoring.

Study design:
Prospective Observational Cohort Study

Study population:
Patients with PCR confirmed COVID-19 admitted to the hospital, who are 18 years or older

Main study parameters/endpoints:
The main endpoint is the identification of pro-inflammatory biomarkers and cellular immune biomarkers in the development of acute severe lung injury and multi-organ failure in infection with SARS-CoV-2

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The burden of this study for the participants is related to extra blood samples and nasal swabs. Therefore, the risk is 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.

Doel van het onderzoek

N/A

Onderzoeksopzet

During hospital admission: every Monday, Wednesday and Friday and 6 weeks after hospital stay.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Hospitalized patient with PCR confirmed COVID-19 infection
- Eighteen years or older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not able to give consent by representative of the subject

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-04-2020
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	07-05-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8589
Ander register	METC Leiden-Den Haag-Delft : METC LDD P20.046

Resultaten

Samenvatting resultaten
N/A