Covid High-intensity Immunosuppression in Cytokine release syndrome

Gepubliceerd: 23-04-2020 Laatst bijgewerkt: 13-12-2022

Patients with COVID-19 related CRS treated with immunosuppressive treatment have better clinical outcomes compared to patients treated according to standard care.

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

Samenvatting

ID

NL-OMON20650

Bron
Nationaal Trial Register

Verkorte titel
CHIC

Aandoening

COVID-19 pneumonia

Ondersteuning

Primaire sponsor: Zuyderland Medical Center
Overige ondersteuning: so far none specific

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Time to clinical improvement: defined as the time from start of immunosuppressive treatment to improvement of at least 2 points on an ordinal scale 1-7 or hospital discharge, whichever comes first. This endpoint is recommended by WHO and used as the primary

endpoint in the Lopinavir-Ritonavir trial. (17) The ordinal scale categories are: 1) non-hospitalized, able to resume normal activities; 2) non-hospitalized, but unable to resume normal activities; 3) hospitalized, not requiring oxygen therapy; 4) hospitalized, requiring additional oxygen therapy; 5) hospitalized, requiring high-flow nasal oxygen therapy, non-invasive mechanical ventilation, or both; 6) hospitalized, requiring ECMO, mechanical ventilation, or both; and 7) death.

Toelichting onderzoek

Achtergrond van het onderzoek

Patients diagnosed with COVID-19 and severe pulmonary involvement (COVID-19 pneumonia; CORADS >=4) who present to the emergency department with compromised respiratory status (O2 requirement) are screened for treatment protocol. A CRS is deemed to exist if at least two of the following three criteria are met: CRP>100; Ferritin>900, D-Dimers>1500. After informed consent, patients are treated with methylprednisolone (MP) receive 250mg bolus intravenously, followed by at least 4 days MP 1mg/kg body weight iv (bolus). If the clinical situation deteriorates or does not improve after 48 hours, a single tocilizumab (8mg/kg body weight) is added.
Patients are monitored daily in a 24/7 multidisciplinary consultation responsible for treatment decisions, with emphasis on immunosuppressive regime and optimal anticoagulation. Outcome measures are collected up to 6 months after admission: mortality, discharge, ICU admission, respiratory status (including oxygen support) and 3- and 6-month functionality and QoL.
The results of this cohort study will be compared with the results of age-gender and prognostic factor-matched control patients with COVID-19 pneumonia from before the start date of the protocol (1-4-2020). This concerns more than 400 patients.

Doel van het onderzoek

Patients with COVID-19 related CRS treated with immunosuppressive treatment have better clinical outcomes compared to patients treated according to standard care.

Onderzoeksopzet

3, 5, 7, 10, 14, 28 days and 3 and 6 months

Onderzoeksproduct en/of interventie

Methylprednisolone, eventually supplemented by tocilizumab

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligibility for immunosuppressive treatment is based on the Zuyderland treatment protocol (named; ‘Standpunt werkwijze behandeling COVID Zuyderland’, due to frequent updates will the most recent version be leading at any time).
According to Zuyderland treatment protocol version from 01.04.2020, this means:
1. Detection of diffuse interstitial pneumonia or bilateral infiltrations on chest x-ray or CO-RADS score ≥4 based on CT-thorax findings
2. Oxygen saturation at rest in ambient air ≤ 94% or tachypnea ≥30/min.
3. Presence of at least 2 of the following risk factors for CRS
a. High ferritin (> 900 ug/L or two times the level at admission within 48 hours)
b. High C-reactive protein (> 100 mg/L)
c. High D-dimer (> 1500 ug/L)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No specific exclusion criteria

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-04-2020
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-04-2020
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	NL8551
Ander register	Bureau Wetenschappelijk Onderzoek Zuyderland Medical Center : Z2020077

Resultaten