Pre-emptive tocilizumab in hypoxic COVID-19 patients, a prospective randomized trial

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Based on literature we assume a 20% day 30 mortality of patients admitted to the hospital ward with COVID-19. We aim to lower this day 30 mortality to 10%.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20031

Bron
NTR

Verkorte titel
PreToVid

Aandoening

COVID-19 with Hypoxia

Ondersteuning

Primaire sponsor: UMCG, Roche
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

30-day mortality (from randomization)

Toelichting onderzoek

Achtergrond van het onderzoek

This trial aims to develop an effective treatment strategy for COVID-19 patients with hypoxia OR other signs of hyperinflammation (ferritin >2000 µg/L or doubling of serum ferritin in 20-48 hours). The rationale for tocilizumab is: 1) Patients with respiratory failure caused by COVID-19 have a dismal prognosis; 2) The hyper inflammatory state in COVID-19 patients is a main reason for respiratory insufficiency and dead; 3) Tocilizumab is an effective drug to control cytokine storms without hampering the functional immune response; 4) Extensive experience is present with tocilizumab in the clinical setting with cytokine release syndromes (e.g. after CAR-T cell therapy).
The rationale to apply tocilizumab in the pre-emptive phase i.e. at the moment of hypoxia (defined according to cytokine release syndrome (CRS) grade II), or other signs of hyperinflammation (ferritin >2000 µg/L or doubling of serum ferritin in 20-48 hours), is to modulate the cytokine storm at an early phase before the phase of respiratory failure is reached. This is in line with the early application of tocilizumab in the clinical setting to modulate cytokine storms after CAR-T cell therapy.

Doel van het onderzoek

Based on literature we assume a 20% day 30 mortality of patients admitted to the hospital ward with COVID-19. We aim to lower this day 30 mortality to 10%.

Onderzoeksopzet

at entry, prior to first infusion, and 24h, 72h, 1 week, 2 weeks, 3 months after first infusion

Onderzoeksproduct en/of interventie

Patients in this study are treated with intravenous tociluzumab: 8 mg/kg (maximum dose 800 mg), which can be repeated at the same dose after 8 hours if the hypoxia has not improved. This is the approved dose for cytokine release syndrome.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

♦ Patients 18 years and older
♦ Patients with a diagnosis of COVID-19 based on a compatible clinical presentation AND a positive SARS-CoV-2 PCR on a respiratory sample such as a nasopharyngeal swab, sputum, or BAL fluid
♦ Clinical features compatible with hyperinflammation:
- Hypoxia, without other explanation for hypoxia than COVID-19 OR
- ferritin >2000 µg/L or doubling of serum ferritin in 20-48 hours
Hypoxia is defined according to ASTCT CRS Consensus grading: grade II. [Lee DW, et al. BBMT 2019;25(4):625-638] Inclusion of patients already requiring oxygen administration prior to COVID-19 should be discussed with the study team.
♦ Written informed consent.
♦ Patient is capable of giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

♦ Pregnancy
♦ allergy to tocilizumab

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-04-2020
Aantal proefpersonen:	354
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-04-2020
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	NL8504
Ander register	METc UMCG : METc 2020/172

Resultaten