A Phase I-II study of virus neutralizing antibodies against SARS-CoV-2. A focus on convalescent plasma and hyperimmune anti-SARS-CoV2 immunoglobulines

Gepubliceerd: 29-03-2021 Laatst bijgewerkt: 18-08-2022

Primary Objective: • To create a population pharmacokinetic model of SARS-COV-2 neutralizing antibodies as present in ConvP. • To create a population pharmacokinetic model of SARS-COV-2 neutralizing antibodies as present in Nanogam plus Secondary…

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

Samenvatting

ID

NL-OMON22629

Bron
NTR

Verkorte titel
ConvP COVig PK/PD study

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

● Pharmacokinetics of virus neutralizing antibodies of ConvP
● Pharmacokinetics of virus neutralizing antibodies of Nanogam®plus

Toelichting onderzoek

Achtergrond van het onderzoek

Convalescent plasma (ConvP) from recovered COVID-19 patients has been used as a form of treatment against COVID-19 across the globe. However, more than a year into the pandemic, proper dose finding studies are still lacking and its effectivity as a therapy for certain COVID-19 subpopulations remains to be proven by large well designed clinical trials. More recently 2 batches of intravenous immunoglobulins (IVIG) produced from a large pool of ConvP donors were produced by Sanquin Plasma Products B.V. (SPP). As a result of the donor selection process, this IVIG solution (Nanogam®) contains high titers of SARS-CoV-2 neutralizing antibodies and is informally called Nanogam®plus. Compared to ConvP, Nanogam®plus has the advantage of smaller volumes, higher antibody titers, no dose variation and no need for ABO blood group matching. Patients who lack B-cell immunity (by dysfunction or depletion) are at a higher risk for poor outcome and death in case of COVID-19 disease and will have limited or no benefit from vaccination. In these patients ConvP or Nanogam®plus could be used as a prophylactic therapy to protect them from COVID-19 until cohort immunity is present. Below we describe a fase I-II dose finding study of ConvP and Nanogam®plus in B-cell depleted patients with emphasis on pharmacokinetics and exploration on protective effects of antibodies.

Doel van het onderzoek

Primary Objective:
• To create a population pharmacokinetic model of SARS-COV-2 neutralizing antibodies as present in ConvP.
• To create a population pharmacokinetic model of SARS-COV-2 neutralizing antibodies as present in Nanogam
plus

Secondary Objective(s):
• To evaluate the protective potential against COVID-19 in B-cell depleted patients receiving Nanogam

plus or ConvP

• Evaluate the safety of ConvP and Nanogam

plus

Onderzoeksopzet

Evalutation of patient serum on D0; +1 hour; 3, 7, 14, 28 days; 6, 8, 12, 18, 24 weeks

Onderzoeksproduct en/of interventie

Infusion of convalescent plasma or Nanogam plus (IVIG-therapy containing anti-SARS-CoV-2 antibodies)

Contactpersonen

Publiek

Erasmus MC
Bart Rijnders

+31650033572

Wetenschappelijk

Erasmus MC
Bart Rijnders

+31650033572

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years or older
- Informed consent
- B-cell depleted status because one of following:
* Prior B-cell depletion therapy (latest administration < 6 months prior to inclusion)
* Common variable immunodeficiency requiring IVIG suppletion

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
● Symptoms of respiratory infection at time of inclusion
● Anti-SARS-CoV2 antibodies prior to administration of study product
● Positive SARS-CoV-2 PCR
● Known previous history of transfusion-related acute lung injury
● Known IgA deficiency
● Liver cirrhosis
● Known hypersensitivity to human immunoglobulins
● Received anti-SARS-CoV-2 vaccination in the 4 weeks preceding screening or baseline

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	104
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:	29-03-2021
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	NL9379
Ander register	METC Erasmus MC : MEC-2021-0163

Resultaten