Convalescent plasma from cured coronavirus disease (COVID) patients as a therapy for patients with severe COVID disease (CONCOVID)

Published: 27-03-2020
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PrimaryDecrease COVID-19 mortalitySecondary• Evaluate the effect of 300ml convP on hospital stay and the change in WHO disease severity score• Evaluate the effect of 300ml convP on mortality in patients admitted to the ICU • Evaluate the effect of...

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

Summary

ID

NL-OMON50016

Source
ToetsingOnline

Brief title
CONCOVID

Condition

- Viral infectious disorders

Synonym
Coronavirus, COVID-19, SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: convalescent, COVID-19, plasma, SARS-CoV-2

Outcome measures

Primary outcome

• Overall mortality until discharge from the hospital or a maximum of 60 days after admission whichever comes first

Secondary outcome

• Impact of 300ml convP therapy on hospital days

• Change in 8-point WHO COVID19 disease severity scale on day 15

• Change in the 8-point WHO COVID19 disease severity scale on day 30

• Change in the 8-point WHO COVID19 disease severity scale on day 15 in the subgroup of patients with a baseline neutralizing antibody titer (PRNT50) <80.

• Impact of 300ml convP on weaning from oxygen therapy

• Impact of 300ml convP on overall mortality in patients not admitted to the ICU within 24 hours after admission

• Impact of 300ml convP on overall mortality in patients admitted to the ICU within 24 hours after admission

• Difference in the effect of convP on mortality in patients with a duration of symptoms < or * the median duration of symptoms in the study population

• Impact of 300ml convP therapy on ICU days in hospital days in patients admitted to the ICU within 24 hours after admission

• Impact of plasma therapy on the decrease in SARS-CoV2 shedding from airways.

• Impact of CTL, B- and NK cell immunity on disease severity and the likelihood

of being protected from immune plasma transfer.

• Safety of convP therapy

• Impact of plasma therapy on risk of long term inflammation, structural lung

damage and lung function and QoL

• Development of, and predictors for, anti-SARS-CoV2 immune memory.

Study description

Background summary

Immunization with immunoglobulins is occasionally used as therapy for the treatment of viral infectious disease. For example CMV disease, VZV disease, rabies and hepatitis B. Neutralizing antibodies have been found against SARS-CoV-2 present in patients who have been infected with SARS-CoV-2. During the 2003 SARS outbreak, convalescent plasma from SARS recovered donors was shown to increase the discharge rate. With no proven effective therapy against COVID-19, this protocol describes use of convalescent plasma from COVID-19 recovered donors.

Study objective

Primary
Decrease COVID-19 mortality

Secondary
• Evaluate the effect of 300ml convP on hospital stay and the change in WHO disease severity score
• Evaluate the effect of 300ml convP on mortality in patients admitted to the ICU
• Evaluate the effect of 300ml plasma therapy on hospital days for patients admitted to the ICU within 24 hours after admission
• Evaluate the impact of plasma therapy on the decrease in SARS-CoV2 shedding from airways.
• Evaluate the safety of plasma therapy
• Evaluate the impact of plasma on long term inflammation, lung function, functional impairment and QoL.
• Evaluate the impact of inflammation, immune function, and anti-SARS-CoV2 immunological responses on disease severity and plasma efficacy
• Evaluate long-term anti-SARS-CoV2 memory development

Study design

This trial is a randomized comparative trial. Patients will be randomized between infusions with 300mL mL plasma or standard of care therapy

Intervention

Patients will be randomized between infusions with 300mL plasma retrieved from donors or no plasma

Study burden and risks

Benefits of this study may include shorter stay in hospital and a decrease in mortality. Risks of plasma infusion is comparable to risks associated with regular bloodtransfusions. These include transfusion reactions, transfusion related acute lung injury (TRALI) and transmission of (unkown) transmittable diseases. Precautions will be taken against these risks

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

Patients
• Patients with PCR confirmed COVID disease
• The most recent PCR positive sample is <96hrs old
• Patient admitted to the hospital <7 days
• Age >=18
• Written informed consent by patient or legal patient representative

Donors:
• Tested negative for HIV, HBV, HCV, HEV, HTLV and syfilis
• A history of COVID infection that was documented by PCR
• Known ABO-Resus(D) blood group
• A screening for irregular antibodies with a titer <= 1:32
• Asymptomatic for at least 14 days
• Written informed consent regarding the plasmapheresis procedure

Exclusion criteria

Patients
• Participation in another intervention trial on the treatment of COVID-19 that falls under the
Dutch law human research (WMO)
• Already on mechanical ventilation for >96hrs
• IgA deficiency

Donors:
• Age <18 years or age >65 years
• Weight <50 kg
• Medical history of heart failure
• History of transfusion with red blood cells, platelets or plasma after 01-01-1980
• History of organ- or tissue transplant
• A cumulative stay in the United Kingdom of >= 6 months in the period between 01-01-1980 and
31-12-1996
• A history of i.v. drug use
• Insulin dependant diabetes

• An underlying severe chronic illness (i.e. history of heart failure, cancer or stroke)
• Tested positive for HLA- or HNA-antibodies

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2020
Enrollment:	426
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	24-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL73489.078.20

Study results

Date completed:	02-06-2021
Actual enrolment:	87