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Effect of convalescent plasma in early course of COVID-19 disease

Submission date
01/09/2021

Recruitment status
No longer recruiting

Registration date
02/09/2021

Overall study status
Completed

Last Edited
03/09/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
World knowledge about COVID-19 infection is accumulating and data about the clinical presentation of infected patients is ongoing. Common known treatments, including ribavirin and interferon, however, lack evidence. Although drugs with specific anti-coronavirus avidity have been identified, as yet only anti-inflammatory interventions for COVID-19 have been approved. Previous reports on other viral infections including SARS have suggested that convalescent plasma (CP) or serum is effective where no other treatment is available or in an emergency. Convalescent plasma therapy uses blood from people who've recovered from an illness to help others recover.
Access to Convalescent Plasma therapy in a low-resource setting is enabled by the novel filtration device Hemoclear, which is easy to implement. Equitable access to such methods allows readiness in case of viral mutations or new pandemics.

Who can participate?
Patients (aged 18 years or above) with laboratory-confirmed COVID-19 who are admitted to the non-ICU ward with respiratory failure

What does the study involve?
Following informed consent, patients will be randomized into one of two groups: one group will receive 220 ml of convalescent plasma and the other group will receive a similar volume of NaCl 0.9%.

What are the possible benefits and risks of participating?
Benefits of this study may include shorter stay in hospital and a decrease in mortality. The risks of plasma infusion are comparable to risks associated with regular blood transfusions. These include transfusion reactions and transmission of (unknown) transmittable diseases. Maximal precautions will be taken against these risks.

Where is the study run from?
Academic Hospital Paramaribo (Suriname)

When is the study starting and how long is it expected to run for?
June 2021 to April 2022

Who is funding the study?
Academic Hospital Paramaribo (Suriname)

Who is the main contact?
Dr Rosita Bihariesingh-Sanchit, bihariesingh@hotmail.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
IAG.2492-2021

Study information

Scientific Title
SURCOVID trial: A randomized controlled trial using convalescent plasma early during moderate COVID-19 disease course in Suriname

Acronym
SURCOVID

Study objectives
The primary objective of this study is to examine the effect of early convalescent plasma administration in the COVID non-ICU ward on clinical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2021, Suriname Ministry of Health's Ethics Review Board (Henck Arron straat 64, 0000 Paramaribo, Suriname; +597 474941; secdir.volksgezondheid@gov.sr), ref: IAG.2492-2021

Primary study design
Interventional

Study design
Open-label randomized prospective clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
After referral to the the non-ICU COVID-19 ward, the patients were treated with dexamethasone standard therapy. After being randomized by sealed envelope the patients receive convalescent plasma or placebo treatment added to the standard therapy.

An interim-analysis for efficacy and harm will be performed on the primary endpoint when 50% of patients have been included and have been followed up for at least 30 days, and follow-up will continue until discharge or death before day 60.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
COVID-19 convalescent plasma

Primary outcome(s)
Development of severe respiratory disease, defined as a respiratory rate of 30 breaths per minute or more, an oxygen saturation of less than 93% while the patient was breathing ambient air, or both, measured for up to 60 days from baseline.

Key secondary outcome(s)
Measured using patient records:
1. Clinical status assessed by the ordinal scale on days 0, 3, 7, and 15 [Time Frame: up to 15 days]
2. The differences in oxygen intake methods [Time Frame: up to 15 days]
2.1. No need for supplemental oxygenation
2.2. Nasal catheter oxygen inhalation
2.3. Mask oxygen inhalation
2.4. Noninvasive ventilator oxygen supply
2.5. Invasive ventilator oxygen supply
3. Duration (days) of supplemental oxygenation [Time Frame: up to 15 days]
4. Duration (days) of mechanical ventilation [Time Frame: up to 15 days]

5. The mean PaO2/FiO2 [Time Frame: up to 15 days] if applicable
6. The detection frequency could be increased according to the clinician's decision
7. Time to COVID-19 negativity in respiratory tract specimens [every 3 days] [Time Frame: up to 15 days]
8. Dynamic changes of COVID-19 antibody titer in blood [Time Frame: up to 15 days]. The antibody titer is detected on days 0, 3, 7 and 15.
9. Dynamic changes of IL-6 levels in blood [Time Frame: up to 15 days]. The titer is detected on days 0, 3, 7 and 15
10. MCU/ICU admission
11. Length of MCU/ICU (days) [Time Frame: up to 28 days]
12. Length of hospital stay (days) [Time Frame: up to 28 days]
13. All cause mortality [Time Frame: up to 28 days]

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. COVID-19 positive patients who have understood and signed the informed consent
2. Aged ≥18 years
3. Hospital admitted patients with moderate COVID-19 to the non-ICU ward: Laboratory confirmed infection with COVID-19.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Severe or life threatening respiratory disease upon admission
2. Viral pneumonia with other viruses besides COVID-19
3. Ineligible for Convalescent Plasma Therapy
4. Participation in other studies.
5. Other circumstances in which the investigator determined that the patient is not suitable for the clinical trial
6. Refusal of informed consent study participation by Donor and/or Patient
7. Known IgA deficiency

8. Medical conditions in which receipt of 220 ml volume may be detrimental to the patient (e.g. decompensated congestive heart failure)
9. Females who are pregnant or breast feeding

Date of first enrolment
01/09/2021

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
Suriname

Study participating centre
Academic Hospital Paramaribo
Flustraat 1-3
Paramaribo
Suriname
-

Study participating centre
Wanica Regional Hospital
Vredenburg Serie B #39
Lelydorp
Suriname
-

Sponsor information

Organisation
Academic Hospital Paramaribo

ROR
https://ror.org/01ky0w731

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academisch Ziekenhuis Paramaribo [Academic Hospital Paramaribo]

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	22/06/2021	02/09/2021	No	Yes
Protocol file	version 1.2	12/06/2021	02/09/2021	No	No