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Effect of convalescent plasma therapy on intensive care unit (ICU) deaths from COVID-19 in Suriname

Submission date
11/04/2021

Recruitment status
No longer recruiting

Registration date
13/04/2021

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

COVID19 remains a global health threat and reliable treatment is crucial for reducing mortality and the burden on global health care. SARSCoV2specific therapies, including convalescent plasma (CP) from recovered patients, could be highly effective options to treat COVID19 in the absence of widespread vaccination. As such, CP therapy may help bridge the gap until sufficient vaccination coverage has been reached. Access to Convalescent Plasma therapy in a low-resource setting was enabled by the novel filtration device Hemoclear, which was easy to implement in an intensive care unit (ICU) setting and was used without adverse effects on both the donor as the CP recipients. Access to these methods will allow readiness in case of viral mutations or new pandemics.

This study aims to investigate whether a new CP production method can provide an effective CP treatment for patients with severe or life-threatening COVID-19 in combination with standard treatment. This study could also help to demonstrate whether the new CP production method could be a practical solution for low and middle-income countries (LMICs) to produce CP locally.

Who can participate?
Adult patients admitted to the Intensive Care Unit of Academic Hospital Paramaribo or the Wanica Regional Hospital, Suriname with severe or life-threatening COVID-19

What does the study involve?
Eligible participants will be allocated to one of two groups, to receive CP treatment in combination with standard care, or to receive standard care only. Participants will undergo chest

x-ray scans and blood tests at the start of the study and after 2 days of treatment and patient survival after 28 days will also be recorded.

What are the possible benefits and risks of participating?
Rapid recovery from respiratory failure due to COVID-19 can occur after passive immunization by convalescent plasma administration. This is plasma from cured patients that contain antibodies that are capable to attack the virus. During or after transfusion the following side effects of fever, chills, hives, itching, or red skin can occur. These complaints occur within a few hours and can be remedied with medication.

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

When is the study starting and how long is it expected to run for?
From June 2020 to December 2020

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Mortality reduction in ICU-admitted COVID-19 patients in Suriname after treatment with convalescent plasma acquired via gravity filtration

Acronym
SuriCovid

Study objectives
The added use of convalescent plasma produced by a gravity driven filtration device will improve ICU clinical outcome if added to standard treartment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/06/2020, Suriname Ministry of Health’s Ethics Review Board (Henck Arronstraat 64, Paramaribo, Suriname; +597 477601; secretariaat.directeur@health.gov.sr), ref: IGAP02-482020

Study design
Open-label non-randomized prospective clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions

Adult patients admitted to the Intensive Care Unit of Academic Hospital Paramaribo or the Wanica Regional Hospital, Suriname with severe or life-threatening COVID-19 were enrolled in the trial. After referral to the ICU, the patients were treated by supportive therapy such as additional respiratory and circulatory support. Participants were allocated to receive either standard treatment including dexamethasone or, if being found eligible for convalescent plasma (CP) treatment and providing informed consent for treatment to receive CP, recieved CP in addition to standard treatment. The CP arm will receive two units of 220 ml convalescent plasma infused in addition to standard supportive ICU treatment. The follow-up period will be 28 days.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Convalescent plasma

Primary outcome(s)
28-day ICU mortality measured from patient records at 28 days

Key secondary outcome(s))
1. Lung function measured as pulmonary oxygen exchange capacity (PF ratio) calculated from arterial blood gas and patient oxygen requirements at baseline and 2 days
2. Extent of lung abnormalities measured as chest x-ray (CXR) score calculated from CXR scans at baseline and 2 days

Completion date
10/01/2021

Eligibility

Key inclusion criteria
1. Polymerase chain reaction (PCR) confirmed COVID-19 disease
2. Aged >18 years
3. Written informed consent to participate in the study from the patient, or legal patient representative if the patient is unconscious (spouse or 1st-degree family member, and if absent 2nd-degree family member or acquaintance)
4. Admittance to the ICU due to progressive respiratory failure ranging between severe and life-threatening ARDS based on the Berlin classification
5. Requiring non-invasive ventilation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
78

Key exclusion criteria
1. Requiring invasive ventilation
2. A “no ICU admission” or “no invasive ventilation” restriction in place at the time of screening for the study
3. Admitted to the COVID-19 ward but asymptomatic, admitted due to the national admission policy, or mild SARS-CoV2

Date of first enrolment
03/06/2020

Date of final enrolment
30/12/2020

Locations

Countries of recruitment
Suriname

Study participating centre
Academic Hospital Paramaribo
Flustraat
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
Academic Hospital Paramaribo

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/02/2023	12/06/2023	Yes	No