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A study comparing two methods to obtain COVID -19 convalescent plasma: the hemofiltration method using gravity and the centrifugation method with spinning forces

Submission date
05/04/2022

Recruitment status
No longer recruiting

Registration date
11/04/2022

Overall study status
Completed

Last Edited
11/04/2022

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
Plasma containing antibodies against COVID-19 (convalescent plasma) can be used for the treatment of newly admitted patients who have just been infected with COVID-19. The aim of this study is to compare two methods to make COVID-19 convalescent plasma. One uses the HemoClear blood filter and the other is the gold standard method by centrifuge which takes place at the National Blood Bank. The plasma obtained will be further analyzed for components to determine its effectiveness against COVID-19.
Studies on the use of COVID-19 convalescent plasma are still ongoing worldwide. In Suriname, a reduction in the risk of death was seen in the Intensive Care Unit patients when using COVID-19 convalescent plasma compared with patients without additional plasma treatment. The use of the HemoClear blood filter has been proven to be effective as a method to get COVID-19 convalescent plasma. This method can also be applied under conditions with limited electricity, space and finances. Further evaluation of COVID-19 convalescent plasma is now appropriate. The research has been approved by the medical ethical review committee of the Ministry of Health of Suriname. Together we can fight the virus.

Who can participate?
Healthy volunteers aged 18 years and over who have been cured of COVID-19 and have been free of symptoms for at least 2 weeks (no more coughing, no fever, no cold symptoms, sense of taste and smell are back). Participants must weigh at least 50 kg, must never have received blood or plasma transfusions in the past, and must not have Hepatitis B, C, HIV or syphilis or have experienced one of these infections.

What does the study involve?
Participants register at the Academic Hospital Paramaribo and are welcomed by Dr Bihariesingh (location second floor, operating room) and her team. They will receive an operating room jacket and slippers over their footwear. After that they will be accompanied to the sterile room where the procedure will start. Heart rhythm, blood pressure and oxygen levels in the blood are

monitored. An infusion needle is inserted and participants are given a liquid infusion of 500 ml. After that, the donation procedure begins. 500 ml of blood is donated which is intended for the National Blood Bank of the Surinamese Red Cross for processing for COVID-19 convalescent plasma. This plasma will ONLY be used for analyses and therefore will not be administered to patients. The erythrocyte or red blood cell concentrate will NOT be used by the blood bank and will be destroyed. After the first donation, 500 ml of blood is donated additionally. From this, COVID-19 convalescent plasma is obtained through the use of the HemoClear blood filter. The erythrocytes (red blood cells) are returned back to the participant after filtration.

What are the possible benefits and risks of participating?
The researchers cannot compensate participants in these exceptional circumstances. This research is organized without any financial support. Participants will receive the great gratitude of the medical staff and the patients they hope to help with this.
Taking blood from the arm can sometimes lead to bruising, mild pain or discomfort and in very rare circumstances, infection of the infusion site. The researchers will take all preventive measures to minimize these risks. Some people may feel light-headed or slightly dizzy, especially while donating plasma. This only takes a few minutes and decreases quickly.
All information provided and all test results will be treated confidentially. The medical staff have the responsibility to inform the participants of all blood test results and to advise them on any treatment they think they need.

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 December 2021

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

Who is the main contact?
Dr Rosita Bihariesingh-Sanchit
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Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CMWO:01/2022

Study information

Scientific Title
Surplasma Access Trial: a prospective paired sample study comparing gravity-driven cross-flow membrane and mechanical centrifugal convalescent COVID-19 plasma production procedures

Acronym
Surplasma COVID-19

Study objectives
Harvesting COVID-19 convalescent plasma via centrifugation or hemofiltration differs in the procedural results and in the final cellular components of convalescent plasma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/03/2022, Suriname Ministry of Health Ethics Review Board (Henck Arronstraat 64, Paramaribo, Suriname; +597 (0)477601; secretariaat.directeur@health.gov.sr), ref: CMWO 01 /2022

Study design
Prospective paired sample study

Primary study design
Observational

Study type(s)
Other

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

Interventions

This is a prospective paired sample study where whole blood from each chosen patient is used for harvesting COVID-19 convalescent plasma using both the Hemoclear filter device and the centrifugal method by spinning at 3400 rpm for 10.22 minutes. Blood samples will be collected pre- and post-processing for analysis. This setup will allow direct comparison of both methods.

The procedure is performed by the anesthesiologist of the Academic Hospital of Paramaribo in the recovery or operating room environment. The donor is installed and monitored on vital signs, a peripheral line is placed for donation (and reinfusion of the cellular components after the procedure). The donor will receive a 500 ml infusion of Ringer's solution (Baxter) prior to donation in order to compensate beforehand for the procedural blood withdrawal.

The first donated 500 ml of whole blood will be processed at the National Blood Bank. The donor will receive a 500 ml infusion of Ringer's solution (Baxter) prior to donation in order to compensate beforehand for the procedural blood withdrawal.

The centrifugation procedure will be performed in the lab of the National Blood Bank by spinning this volume at 3400 rpm for 10.22 minutes in order to obtain the separation. The red blood cells (300 ml) will not be used.

The donor will continue with the second donation process by filtration. 500 ml of whole blood will be filtrated by the Hemoclear filter method. The residual red blood cells (200-300 ml) and platelets are reinfused into the donor at the end of each filtration procedure.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hemoclear filter, Hettich Rotanta Silenta 630 RS centrifugation system

Primary outcome(s)
Total antibody load per ml in convalescent plasma, measured using a validated spike protein ELISA assay at the timepoint of production of convalescent plasma by either the centrifugal or microfiltration method (t1)

Key secondary outcome(s))
1. Procedure time, including setup and priming of the hemoclear filter and centrifugation system, measured as the time between the start of set-up (t0) and finishing the convalescent plasma procedure (t1)
2. Blood cell losses measured using Hemaocrit in convalescent plasma at timepoint t1 compared with whole blood Hematocrit at the donation timepoint (td)
3. Levels of IgG, IgM , IgA and fibrinogen measured from whole blood after collection of donor blood (td). After processing and production of convalescent plasma, samples are drawn to perform the same measurements (t1) in order to calculate the efficacy of removal.
4. Virus neutralization determined by measuring plasma neutralizing antibodies (nAbs) in the samples after production of CP (t1). The total plasma levels of antibodies against spike region S1 are measured using an ELISA assay. The nAb titer will be calculated as the highest plasma dilution that eliminated the cytopathic effect in 50% of the wells (NT50).

Completion date
21/12/2021

Eligibility

Key inclusion criteria
1. Were sick with a coronavirus infection (but do not need to have been hospitalized). Free of symptoms for at least 2 weeks (no more coughing, no fever, no cold symptoms, taste and smell are back). The infection must be proven by a test from B.O.G. or the Academic Hospital.
2. Weigh at least 50 kg
3. At least 18 years old
4. Never received blood or plasma transfusions in the past
5. In good health
6. Not have or not previously had hepatitis B, C, HIV or syphilis. This will be tested for. If participants do not want to know, they cannot participate in this study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
10

Key exclusion criteria
Have or have previously had hepatitis B, C, HIV or syphilis or do not want to be tested for this

Date of first enrolment
01/09/2021

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
Suriname

Study participating centre
Academic Hospital Paramaribo
Flustraat 1-3
Paramaribo
Suriname
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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 will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			07/04/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			07/04/2022	No	No