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Plasma treatment for COVID-19

Submission date 28/06/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/07/2025	**Overall study status** Completed	
Last Edited 14/07/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
The study was intended to assess the use of plasma therapy in COVID-19. The study recruited COVID-19-positive patients who were classified as moderate or severe cases. The implementing agency of this study is the University of the Philippines Manila, and the recruitment site is at the Lung Center of the Philippines. The study was recruited starting on December 01, 2020 until November 11, 2024. This study was funded by the Philippine Council for Health Research and Development. For further information, you may reach out to Dr. Jose B. Nevado, Jr

Who can participate?
COVID-19-positive patients who were classified as moderate or severe cases at the Lung Center of the Philippines

What does the study involve?
The participants in the treatment arm received plasma transfusions (up to 8 units, as tolerated, for 7 days; 2 units every other day, with each unit administered 8 to 12 hours apart) in addition to the local standard of care at that time. Participants in the control arm received only what was considered the current local standard of care.

What are the possible benefits and risks of participating?
Benefits in participating in this study includes coverage of standard of care for COVID-19 patients at the Lung Center of the Philippines. Given the study explores plasma transfusion therapy, risks include Transfusion Related Acute Lung Injury (TRALI), Transfusion associated circulatory overload (TACO) infections, allergy, and hemolysis.

Where is the study run from?
The University of the Philippines Manila, Philippines

When is the study starting and how long is it expected to run for?
April 2020 to December 2024

Who is funding the study?
The Philippine Council for Health Research and Development, Philippines

Who is the main contact?
Dr Jose B. Nevado, Jr., jbnevado1@up.edu.ph

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
RGAO-2020-0839

Study information

Scientific Title

Evaluation of plasma therapy for retarding progression and preventing complications in COVID-19

Study objectives
To explore the impact of plasma transfusion therapy in the treatment of COVID-19 and to analyze candidate immune-related proteins that may influence the hyperinflammatory response

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/08/2020, Lung Center of the Philippines Institutional Ethics Review Board (Lung Center of the Philippines, Quezon Avenue Extension, Quezon City, 1100, Philippines; +63 8924-6101; lcpierb@gmail.com), ref: LCP-CT-021-2020

2. approved 19/04/2020, UP Manila Research Ethics Board (Pedro Gil St, Ermita, Manila, 1000, Philippines; +63 8554-8400 l; upmreb@post.upm.edu.ph), ref: UPMREB 2020-0644-01

Study design
Randomized open-label controlled study design

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Treatment of COVID-19 using plasma repletion therapy

Interventions
The participants in the treatment arm received plasma transfusions (up to 8 units, as tolerated, for 7 days; 2 units every other day, with each unit administered 8 to 12 hours apart) in addition to the local standard of care at that time. Participants in the control arm received only what was considered the current local standard of care.

Computer-generated randomization protocol was used to assign eligible enrolled patients to either the control group (standard of care) or treatment group (plasma transfusion). At the time of randomization, the clinical profile (e.g. with or without co-morbidities) of the individual participant is not known to the investigator in charge of randomization.

All enrolled study participants were under the care of an attending licensed pulmonologist (hospital staff). Prior to the study initiation, the attending pulmonologists (hospital staff) who managed Covid patients were oriented thoroughly with this Covid study protocol. A separate study pulmonologist/investigator - was thorioughly trained to assess patients based on inclusion and exclusion criteria, data gathering captured in case report forms, and administration of interventional agent in the proper dose and frequency as well as reporting of outcomes and any adverse events.

Once the participant is randomized, the study pulmonologist identifies the patient as a study participant and his randomized group. Study pulmonologist legibly writes the orders in the medical chart that corresponds to participant's allocation and study protocol. For the treatment group, transfusion of 250 ml appropriately typed and cross-matched plasma was administered every 12 hours for D0, D2, D4, D6 until a total of 8 bags was given. The rest of the management strategies followed the standard of care as defined by the hospital's clinical pathway algorithm for COVID patient. Management of the participant under the control group followed the hospital's clinical pathway algorithm of standard of care for Covid patient.

A licensed bedside nurse (hospital staff) carried out orders for plasma transfusion. The study pulmonologist visits the participants daily for reporting of outcomes and adverse events. The study pulmonologist has real time access to the medical chart but the attending staff pulmonologist managed the participant.

The intervention was done in emergency rooms and wards of the Lung Center of the Philippines. At the time of the study, the Lung Center of the Philippines, a tertiary level hospital, was a designated hospital for Covid patients.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
250-mL plasma bag from healthy donors

Primary outcome(s)
1. All-cause mortality is measured using vital status from the medical chart at discharge or at 30 days post-enrolment, whichever occurs first
2. Need for ventilator support is measured using clinical decision documented by the primary attending pulmonologist based on arterial blood gas parameters, sensorium, and overall status at any time during hospitalization up to 30 days post-enrolment
3. Prolonged hospital stay is measured using duration of hospital admission from admission and discharge dates recorded in the medical chart at discharge
4. Composite outcome is measured using the count of participants who experienced more than one of the primary outcomes using medical chart review at discharge or at 30 days post-enrolment, whichever occurs first
5. All outcomes are monitored using daily clinical assessments by the study pulmonologist with real-time access to the medical chart from enrolment until discharge or 30 days, whichever occurs first

Key secondary outcome(s))
Assessed from the medical notes/chart during their course of treatment until discharge:
1. The occurrence of shock, defined as mean arterial pressure less than 60 mmHg or the use of inotropic agents (norepinephrine, epinephrine, vasopressin, dopamine, etc) for at least 24 hours
2. Multiorgan failure, defined as progression to severe COVID-19 with any two of the following: presence of acute respiratory distress syndrome (P/F ratio <200)
3. The need for emergent dialysis
4. Presence of cardiac injury or (EF <40), at least threefold increase in AST or ALT or PT INR >2.5)

Completion date
11/12/2024

Eligibility

Key inclusion criteria
1. Aged 18 to 75 years
2. Presenting with dry cough, fever, dyspnea, or gastrointestinal symptoms on admission
3. Positive RT-qPCR test for SARS-CoV-2 RNA
4. Classified as a moderate or severe case of COVID-19 according to the Philippine College of Physicians (PCP)-Philippine Society for Microbiology and Infectious Diseases (PSMID) COVID-19 Guidelines and the updated COVID-19 treatment algorithm at the time of the study
4.1. Moderate COVID-19
4.1.1. With signs of non-severe pneumonia (e.g., fever, cough, dyspnea, or difficulty breathing), respiratory rate of 21-30/minute, oxygen saturation >92% on room air
4.1.2. with any of the following comorbidities: chronic hypertension, diabetes mellitus, chronic lung disease, obesity, chronic renal disease, persistent asthma
4.1.3. With PaO2/FiO2 (P/F) of >300
4.2. Severe COVID-19
4.2.1. With severe pneumonia or severe acute respiratory infection, defined as follows: fever, cough, dyspnea, respiratory rate >30 breaths/minute, severe respiratory distress
4.2.2. With *P/F of 200-300
4.2.2. oxygen saturation <92%, at FiO2 0.6

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
121

Key exclusion criteria
1. Significant lung pathology as defined by P/F ratio<200, or obvious respiratory distress
2. Significant renal impairment as defined by eGFR<30
3. Malignancy
4. Hemodynamic instability such as refractory hypotension or shock

5. Presence of severe neurological deficits
6. Prior blood/plasma transfusion in the past two months
7. Cannot provide independent informed consent due to mental incapability

Date of first enrolment
01/03/2021

Date of final enrolment
30/03/2022

Locations

Countries of recruitment
Philippines

Study participating centre
Lung Center of the Philippines
Quezon Avenue, Barangay Central, Diliman
Quezon City
Philippines
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Study participating centre
University of the Philippines Manila
Padre Faura St. corner Ma. Orosa St., Ermita
Manila
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Sponsor information

Organisation
Philippine Council for Health Research and Development

ROR
https://ror.org/04rpdbq72

Funder(s)

Funder type
Government

Funder Name
Philippine Council for Health Research and Development

Alternative Name(s)
Department of Science and Technology- Philippine Council for Health Research and Development, DOST PCHRD, DOST_PCHRD, PCHRD, DOST-PCHRD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Philippines

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication

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