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City of Hope

IRB# 20204: Evaluation of Coronavirus Disease 19 (COVID-19) Convalescent Plasma

CRF – Patient Participant

MODULE 1: ON THE DAY OF CCP INFUSION (BASELINE-BEFORE INFUSION)

COVID-19 SYMPTOMS PRIOR TO TRANSFUSION

- Shortness of breath
- Cough
- With sputum production
- With haemoptysis
- Chills
- Fatigue/malaise
- Myalgia
- Fever
- Sore throat
- Runny nose
- Wheezing
- Dry cough
- Headache
- Dizziness/light-headedness
- Loss of smell/taste (anosmia/dysgeusia)
- Stomach/abdominal pain
- Vomiting (emesis)/Nausea
- Diarrhea
- Decreased appetite (Anorexia)
- Palpitations
- Chest discomfort/pain (Angina)
- Arthralgia
- Myocarditis
- Inability to walk
- Seizures
- Conjunctivitis
- Blood clot
- Skin rash
- Bleeding (hemorrhage)
- Lymphadenopathy
- Lymphopenia
- Immunosuppressed
- Other
- None

CO-MORBIDITIES (existing prior to admission)

Chronic cardiac disease (not hypertension), if yes, type
Diabetes
Obesity (BMT>)
Hypertension
Smoking history
Pulmonary disease
Tuberculosis
Asthma
Asplenia
Kidney disease
Malignant neoplasm
Chronic liver disease
Chronic neurological disorder ☐Yes ☐No ☐Unk If yes, specify: _____
HIV positive (if yes, CD4<200?)
Hepatitis
On immunosuppressive therapy
History of transplantation
Other:
None

CCP TRANSFUSION

- How many units of plasma were given to patient?
- Date/time of plasma infusion:
  - 1st unit: MM/DD/YYYY, ____:____ AM/ PM

- 2nd unit: MM/DD/YYYY, ____:____ AM/ PM
- Additional unit: MM/DD/YYYY, ____:____ AM/ PM

- Volume of plasma transfused (mL):
  - 1st unit: ____mL
  - 2nd unit: ____mL
  - Additional unit: ____mL
- Plasma Unit Identifying Number(s):
  - 1st unit:
  - 2nd unit:
  - Additional unit:
- Blood bank establishment providing the plasma unit
- Confirm you collected a sample of the plasma unit (≥0.5 mL) for analysis Yes/No
- Number of days from symptom onset to plasma transfusion
- Number of days in hospital prior to plasma transfusion
- Which applies to the patient at the time of infusion (select one)
  - Currently has severe/life-threatening COVID-19
  - At high risk of progression to severe/life-threatening disease (judged by provider)

VITAL SIGNS

Temperature [___][___].[___]°C
Heart rate [___][___][___]beats/min
Respiratory rate [___][___]breaths/min
BP [___][___][___](systolic) [___][___][___](diastolic) mmHg
Oxygen saturation: [__][__][__]% on □room air □oxygen therapy □Unknown A V P U (circle one)
Chest X-Ray /CT performed? If Yes: infiltrates present?
Height: [___][___][___]cm
Weight: [___][___][___]kg
Biomarkers Prior to Transfusion (fill in any available)

Troponin T [___] (ng/mL)
Troponin I [___] (ng/mL)
NT-proBNP [___] (pg/mL)
Creatinine [___] (mg/dL)
Blood Urea Nitrogen (BUN) [___] (mg/dL)
C Reactive Protein (CRP) [___] mg/L, [___] mg/dL
Ferritin [___] ng/ml [___] mcg/L

IL-6 [___] (pg/mL)
IL-10 [___] (pg/mL)
INF-ɣ, [___] (pg/mL)
TNF-α [___] (pg/mL)
D-dimer [___] (ng/mL)
LDH [___] (U/L)
Alpha1-Antitrypsin (AAT) [___] (mg/dL)

SUPPORTIVE CARE

- Is the plasma recipient/patient in the ICU or High Dependency Unit admission? If yes, for how many days?
- Is the plasma recipient/patient hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise)?
- Is the plasma recipient/patient hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care (other than per protocol RDV administration)?
- Highest level of hospital respiratory support prior to transfusion:
  - Non-Invasive Positive-Pressure Ventilation NIPPV (e.g. CPAP, BiPAP, high-flow nasal cannulation)
  - Low flow supplemental oxygen
  - Mechanical ventilation/intubation
  - Extra Corporeal Membrane Oxygenation (ECMO)
  - None
- Oxygen therapy
  - If yes, complete all below O2 flow: •1-5 L/min •6-10 L/min •11-15 L/min •>15 L/min
  - Source of oxygen: Piped Cylinder Concentrator Unknown
  - Interface: Nasal prongs HF nasal cannula Mask Mask with reservoir CPAP/NIV mask Unknown

- Is the plasma recipient/patient in prone position?

MEDICATIONS GIVEN WITHIN 14 DAYS OF CCP INFUSION

- Angiotensin converting enzyme inhibitors (ACE inhibitors)?
- Angiotensin II receptor blockers (ARBs)?
- Non-steroidal anti-inflammatory (NSAID)?
- Azithromycin
- Remdesivir
- Antivirals: ribavirin, Lopinavir/Ritonavir, Neuraminidase inhibitor,Interferon alpha,Interferon beta, Other, specify:
- Steroids: If yes, route: Oral, Intravenous, Inhaled. Please provide agent and maximum daily dose
- Chloroquine
- Hydroxychloroquine
- Oral/orogastric fluids?
- Vasopressor
- Intravenous fluids
- Antibiotic
- Antifungal
- Experimental agent
- Tocilizumab or other anti-cytokine med
- Other

MODULE 2: 24 HOUR DATA COLLECTION POST-EACH PLASMA TRANSFUSION

Serious Adverse Events (SAEs) within 24 hours of transfusion:

- Death
- Transfusion related acute lung injury (TRALI)
- Transfusion related circulatory overload (TACO)
- Transfusion related infection
- Severe allergic transfusion reaction (requiring medical intervention other than antihistamines)
- Severe hemolytic transfusion reaction (requiring medical intervention)
- Severe anaphylactic reaction
- None

Other Serious Events within 24 hours of transfusion (related or not related to transfusion, may reflect natural disease progression) (expect sponsor follow up)

- Need for ICU transfer (since transfusion)
- Need for increased oxygen support (since transfusion)
- Need for mechanical ventilation (since transfusion)
- VF ventricular arrhythmia requiring treatment
- VT ventricular arrhythmia requiring treatment
- Atrial arrhythmia requiring treatment
- Atrial fibrillation requiring treatment
- Cardiac arrest
- Need for ECMO or ventricular assistance
- None

Need for additional IV vasopressor support within 4 hours of transfusion (beyond requirements prior to transfusion)?

MODULE 3: ONE TIME BETWEEN 14-28 DAYS POST FIRST CCP INFUSION, OR AT DISCHARGE FORM THE HOSPITAL OR DEATH, WHICHEVER COMES FIRST

CURRENT COVID-19 SYMPTOMS

- Shortness of breath
- Cough
- With sputum production
- With haemoptysis

- Chills
- Fatigue/malaise
- Myalgia
- Fever
- Sore throat
- Runny nose
- Wheezing
- Dry cough
- Headache
- Dizziness/light-headedness
- Loss of smell/taste (anosmia/dysgeusia)
- Stomach/abdominal pain
- Vomiting (emesis)/Nausea
- Diarrhea
- Decreased appetite (Anorexia)
- Palpitations
- Chest discomfort/pain (Angina)
- Arthralgia
- Myocarditis
- Inability to walk
- Seizures
- Conjunctivitis
- Blood clot
- Skin rash
- Bleeding (hemorrhage)
- Lymphadenopathy
- Lymphopenia
- Immunosuppressed
- Other
- None

VITAL SIGNS/BASELINE

Temperature [___][___].[___]°C
Heart rate [___][___][___]beats/min
Respiratory rate [___][___]breaths/min
BP [___][___][___](systolic) [___][___][___](diastolic) mmHg
Oxygen saturation: [__][__][__]% on □room air □oxygen therapy □Unknown A V P U (circle one)
Chest X-Ray /CT performed? If Yes: infiltrates present?
Biomarkers Prior to Transfusion (fill in any available)

Troponin T [___] (ng/mL)
Troponin I [___] (ng/mL)
NT-proBNP [___] (pg/mL)
Creatinine [___] (mg/dL)
Blood Urea Nitrogen (BUN) [___] (mg/dL)
C Reactive Protein (CRP) [___] mg/L, [___] mg/dL
Ferritin [___] ng/ml [___] mcg/L

IL-6 [___] (pg/mL)
IL-10 [___] (pg/mL)
INF-ɣ, [___] (pg/mL)
TNF-α [___] (pg/mL)
D-dimer [___] (ng/mL)
LDH [___] (U/L)
Alpha1-Antitrypsin (AAT) [___] (mg/dL)

SUPPORTIVE CARE

- Is the plasma recipient/patient in the ICU or High Dependency Unit admission? If yes, for how many days?
- Is the plasma recipient/patient hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise)?
- Is the plasma recipient/patient hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care (other than per protocol RDV administration)?
- Highest level of hospital respiratory support since transfusion:
  - Non-Invasive Positive-Pressure Ventilation NIPPV (e.g. CPAP, BiPAP, high-flow nasal cannulation)
  - Low flow supplemental oxygen
  - Mechanical ventilation/intubation
  - Extra Corporeal Membrane Oxygenation (ECMO)
  - None
- Oxygen therapy
  - If yes, complete all below O2 flow: •1-5 L/min •6-10 L/min •11-15 L/min •>15 L/min
  - Source of oxygen: Piped Cylinder Concentrator Unknown
  - Interface: Nasal prongs HF nasal cannula Mask Mask with reservoir CPAP/NIV mask Unknown
- Is the plasma recipient/patient in prone position?

PRIMARY OUTCOMES POST CCP TRANSFUSION (IF APPLICABLE)

- Reduced supplemental oxygen requirements
- Extubation (if applicable)
- Resolution of Acute Respiratory Distress Syndrome (ARDS) as judged by physician (if applicable)
- COVID-19 symptom improvement
- Discharge from ICU (if applicable)
- SARS-CoV-2 PCR negative
- Discharge from Hospital/ If Discharged alive: Ability to self-care at discharge versus before illness Same as before illness Worse Better Unknown
- Transfer to other facility
- Death
- None

OTHER NEW SEVERE ADVERSE EVENTS WITHIN 28 DAYS OF CCP TRANSFUSION (not previously reported on 24 hour post-transfusion reports; related or not related to transfusion, may reflect natural disease progression).

Appendix F: COVID-19 Severity Grading Score (Pre-Specified Model)

The COVID-19 scoring system was developed as a modification of the HScore developed originally for use in patients with immunopathologic syndromes, e.g. secondary hemophagocytic lymphohistiocytosis (26) and the Cytokine Release Syndrome (27). The rationale behind use of these scoring systems in COVID-19 syndrome is the observation that severity of COVID-19 infection is linked to cytokine storm (13, 28).
The COVID-19 Severity Grading Score is shown in Table 3.

Table 3 COVID-19 Severity Grading Score

Temperature <38C 38.4—39.4 >39.4C	Points 0 20 30		Lowest SaO2 on Room Air ≥ 95% 90-95% <90%	Points 0 20 30
Lymphopenia Yes No	Points 0 30		Ventilator Support No Yes	Points 0 30
Ferritin ng/mL >2.5 g/L <2.5 g/L	Points 0 20		Serum AAT Elevated No Yes	Points 0 20
Immunosuppressed No Yes	Points 0 20		Body Mass Index <25 25-30 >30	Points 0 10 20
TOTAL				