The Use of Convalescent Plasma for Treatment of Patients Hospitalized with COVID-19

A Phase 2 Open Label, Randomized Control Pilot Study to Evaluate the Safety, Tolerability and Efficacy of Convalescent Plasma IRB#13807 FDA IND#21101

For patients with laboratory confirmed COVID-19 who are hospitalized

Inclusion Criteria:

- Age>= 18

With one or more of the following:

- Dyspnea
- RR>= 30
- O2 saturation <= 93%
- PaO2/FiO2 <300mmHg
- Bilateral airspace opacities on CXR >50% within 24 to 48 hours

Exclusion Criteria:

- Participation in any other clinical trial for COVID-19
- Incarceration
- Concurrent treatment with other agents with actual or possible direct acting antiviral activity against SARS-CoV-2 < 24 hours prior to plasma infusion; steroids and/or hydroxychloroquine are allowed along with other standard therapy
- Negative rRT-PCR from nasopharyngeal swab or respiratory secretions within 48 hours prior to eligibility assessment
- History of allergic reaction to blood or plasma products
- Known IgA deficiency
- Acute myocardial infarction within past 30 days
- Acute stroke within past 30 days
- VV-ECMO or VA-ECMO

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Study Procedures:

2:1 randomization (treatment: control)

If patient is randomized to **control arm** and has clinical worsening at 72 hours as documented by one of the following:

1. Respiratory failure requiring intubation for those not intubated at randomization
2. PaO2/FiO2 measured in the supine position worsened by >= 20% over 2 consecutive days

(for example if PaO2/FiO2 at randomization was 200 and now has been <= 160 for the past 2 days)

3. Progression of disease with septic shock
4. Multiple organ dysfunction or failure

Then discuss with Investigators for reassessment for potential plasma

Objectives:

Primary Outcome:

- To evaluate the improvement in oxygenation as documented by PaO2/FiO2 or Sa/FiO2 (if no ABG at enrollment) 72 hours after plasma infusion

Secondary Outcome:

- To evaluate the overall clinical and laboratory improvement after plasma infusion – ventilation days, ICU length of stay, mortality; improvement in Crp, D-dimer, other inflammatory markers

Laboratory Testing

- Screening
  - CBC w/ diff
  - Electrolyte panel
  - Crp
  - IL-6 (if available)
  - D-dimer
  - LDH
  - ABG (if mechanically ventilated)
  - CXR or CT imaging already available
- Days 1,3,5,7,14, and 28
  - CBC w/ diff
  - Electrolyte panel
  - Crp
  - D-dimer
  - LDH
  - ABG (if mechanically ventilated)

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