Passive Immunity Trial for Our Nation to Treat COVID-19 in Hospitalized Adults

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over

Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Age greater than or equal to 18 years of age
2. Currently hospitalized or in an emergency department with anticipated hospitalization
3. Symptoms of acute respiratory infection, defined as one or more of the following: 1. Cough 2. Chills, or a fever (greater than 37.5°C or 99.5°F) 3. Shortness of breath, operationalized as a patient having any of the following: i. Subjective shortness of breath reported by a patient or surrogate. ii. Tachypnea with respiratory rate of greater than 22 breaths per minute. iii. Hypoxemia, defined as SpO2 less than 92% on room air, new receipt of supplemental oxygen to maintain SpO2 greater than or equal to 92%, or increased supplemental oxygen to maintain SpO2 greater than or equal to 92% for a patient on chronic oxygen therapy
4. Laboratory-confirmed SARS-CoV-2 infection within the past 14 days

Exclusion Criteria:

1. Prisoner
2. Unable to randomize within 14 days after onset of acute respiratory infection symptoms
3. Patient, legal representative, or physician not committed to full support (Exception: a patient who will receive all supportive care except for attempts at resuscitation from cardiac arrest will not be excluded)
4. Inability to be contacted on Day 29-36 for clinical outcome assessment
5. Receipt of COVID-19 convalescent plasma or pooled immunoglobulin in the past 30 days
6. Contraindications to transfusion or history of prior reactions to transfused blood products
7. Plan for hospital discharge within 24 hours of enrollment
8. Previous enrollment in this trial
9. Enrollment in another clinical trial evaluating monoclonal antibodies, convalescent plasma, or another passive immunity therapy

Conditions & Interventions

Interventions:
Biological: pathogen reduced SARS-CoV-2 convalescent plasma, Biological: Placebo

Conditions:
COVID-19, Coronavirus, SARS-CoV-2

Keywords:
COVID-19 drug treatment, convalescent plasma

More Information

Contact(s):
Claudia M. Cohn, M.D., Ph.D. - cscohn@umn.edu
Therese M. Chlebeck, BAN - chleb001@umn.edu

Phase: Phase 3
IRB Number:
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