

Randomized Controlled Trial to Test if Convalescent Plasma Can Treat COVID-19 Disease

Investigators with the [Miami Clinical and Translational Science Institute](#) (CTSI) at the University of Miami Miller School of Medicine have launched a phase 2 clinical trial to study if convalescent plasma containing SARS-CoV-2 antibodies is effective in treating COVID-19 positive patients who have been hospitalized with acute respiratory symptoms.



Participants will be randomized and receive either convalescent plasma or a placebo (saline solution).

The trial is part of a collaboration between several Clinical and Translational Science Award (CTSA) hubs, including New York University Grossman School of Medicine, Albert Einstein College of Medicine, Yale University School of Medicine and the University of Texas Health Science Center at Houston. It is funded by the National Center for Advancing Translational Sciences (NCATS).

The New York City CTSA hubs initiated the study at the height of the pandemic. When COVID-19 cases there began to decrease, Miami was seeing a rise in infections and related hospitalizations.

“We knew time was of the essence because this kind of treatment has the potential to save lives,” said [Ralph L. Sacco](#), M.D., M.S., director of the Miami CTSI, and professor and Olemberg Chair of [neurology at the Miller School](#). “When NCATS and our CTSA colleagues approached us to help with this critically important study, the Miami CTSI pulled together a team to rapidly launch this major effort.”

Plasma treatments with SARS-CoV-2 antibodies may be successful in helping people who are sick with COVID-19 fight the virus. Antibodies are what the body’s immune system makes in response to an infection.

They are molecules that circulate in the blood and bind to the virus, preventing it from growing in the body.

Convalescent plasma has been used for more than a century to treat infectious diseases. Previous studies suggest that convalescent plasma may be a helpful treatment for other coronaviruses, including SARS.

Study goals

The goal of the study is to determine if convalescent plasma can prevent the development or reduce the severity of breathing symptoms in people with COVID-19. This would reduce the need for additional oxygen, mechanical ventilation and admission to the intensive care unit.

The trial seeks to enroll 360 people who are 18 years or older and test positive for COVID-19. Eligible participants will be within three days of hospitalization at UHealth Tower and Jackson Memorial Hospital, but not in the intensive care unit or on a ventilator. Participants will be randomized and receive either convalescent plasma or placebo (saline solution).

“Many clinicians at UHealth have made anecdotal observations of the benefits of convalescent plasma on hospitalized patients with COVID-19 infection, however, this needs to be validated by a well-designed, randomized clinical trial,” said [Dushyantha Jayaweera, M.D.](#), associate director of the Miami CTSI and the Miami sites’ lead investigator. “As such, this study was designed to bring together collaborators from around the country to provide an answer to whether this is indeed an effective treatment for COVID-19.”

Additional study investigators for the Miami sites include site co-lead, Yanyun Wu, M.D., medical director of transfusion medicine at UHealth – the University of Miami Health System and Jackson Health System, [Shweta Anjan, M.D.](#), assistant professor of clinical medicine and an infectious diseases specialist at UHealth, and [Jose Castro, M.D.](#), professor of clinical medicine and medical director of infection control

and the Antimicrobial Stewardship Program at UHealth.