NIH expands clinical trials to test convalescent plasma against COVID-19

September 22 2020

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Two randomized, placebo-controlled clinical trials funded by the National Institutes of Health (NIH) are expanding enrollment to further evaluate convalescent plasma as a treatment for patients hospitalized with COVID-19. Preliminary observational studies indicate that convalescent plasma may improve outcomes among severely ill and

hospitalized patients with COVID-19. Prospective, well-controlled randomized trials are needed to generate sufficient data on whether convalescent plasma is effective and safe for the treatment of COVID-19.

Convalescent plasma is blood plasma taken from people who have recovered from COVID-19. It contains antibodies that can recognize and neutralize SARS-CoV-2, the virus that causes COVID-19, as well as other components that may contribute to an immune response.

"The evidence on convalescent plasma as a treatment for severe cases of COVID-19 is promising but incomplete. We need to carry out rigorous randomized control clinical trials to determine how this therapy can improve outcomes," said NIH Director Francis S. Collins, M.D., Ph.D. "While the world waits for an effective vaccine, it is vital that we simultaneously expand the options for available treatments for those currently suffering from the worst effects of this disease."

The trials expect to enroll hospitalized patients across the country at academic and community-based hospitals. Participants will be randomly assigned to receive the treatment or a placebo. Outcomes will be compared with respect to clinical improvement measures and resource needs, such as ventilators. Both trials currently are enrolling participants and anticipate results as early as this fall.

The trials are receiving $48 million in support through Operation Warp Speed (OWS), a collaborative initiative across federal agencies to advance the development, manufacturing and distribution of COVID 19 vaccines, therapeutics and diagnostics.

The National Center for Advancing Translational Sciences (NCATS), part of NIH, will oversee the grant awards through its Clinical and Translational Science Awards (CTSA) Program research network. The

CTSA's Trial Innovation Network (TIN) will play a key role in working to add study sites and enroll patients, including those from communities disproportionately affected by COVID-19.

"The rapid expansion of these vital randomized, controlled convalescent plasma clinical trials demonstrates how nimbly the network of CTSA Program hubs and the TIN can respond to the nation's research needs and shorten the path from discovery to treatment," said NCATS Director Christopher P. Austin, M.D.

One trial, called Convalescent Plasma to Limit COVID-19 Complications in Hospitalized Patients, was launched in April by NYU Langone Health in New York, with collaboration from the Albert Einstein College of Medicine and Yale University, New Haven, Connecticut, and with funding from NCATS. To increase enrollment in the trial, NYU is partnering with The University of Texas Health Science Center at Houston and the University of Miami in Florida to enroll participants at sites in these states.

With these additional sites, this trial expects to enroll approximately 1,000 hospitalized patients 18 years or older with respiratory symptoms of COVID-19. The trial is primarily assessing clinical improvement at 14 and 28 days and also will be evaluating outcomes based on mortality, intensive care unit admission and patient antibody concentrations. Additional information about this study and participation is available at ClinicalTrials.gov under study identifier NCT04364737.

The trial called Passive Immunity Trial of Our Nation for COVID-19 also is expanding to enroll about 1,000 participants. Vanderbilt University Medical Center in Nashville, Tennessee, which launched the trial in April, will have access to about 50 additional clinical trial sites across the CTSA Program. Participants are 18 years or older with acute respiratory infection symptoms and laboratory-confirmed SARS-CoV-2

infection; they may be hospitalized or in an emergency department and likely to be admitted. The trial primarily will assess clinical improvement at 15 days and also will evaluate ventilation use, supplemental oxygen use, acute kidney injury and cardiovascular events. Additional information about this study and participation is available at ClinicalTrials.gov under study identifier NCT04362176.

Provided by National Institutes of Health