UC San Diego UC San Diego News Center

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Does Blood Plasma from COVID-19 Survivors Help Patients Infected with Novel Coronavirus?

A new clinical trial at UC San Diego Health will investigate whether an old therapy might effectively treat a modern-day scourge

There is only one approved, specific treatment for COVID-19, the illness caused by the novel coronavirus SARS-CoV-2, albeit with modest efficacy. Numerous experimental or repurposed drugs are under investigation, including the <u>arthritis drug tocilizumab</u>. And one treatment that is more than a century old.

Researchers at University of California San Diego School of Medicine and UC San Diego Health have launched a clinical trial to assess the safety and efficacy of convalescent plasma (CP) to prevent COVID-19 after a known exposure to the virus. CP therapy involves infusing patients with antibodies extracted from the blood of donors who have



Blood plasma is the yellowish liquid component of blood that holds blood cells in whole blood in suspension. It makes up a little more than half of the body's total blood volume and is comprised mostly of water with added dissolved proteins, sugars, electrolytes, hormones, antibodies and other components.

successfully recovered from COVID-19, with the hope that the resulting boost to their immune systems will shorten the length and reduce the severity of the disease.

The UC San Diego trial is part of a larger, national effort approved by the U.S. Food and Drug Administration. The goal is to create a network of hospitals and blood banks collecting, isolating, processing and testing whether plasma from COVID-19 survivors has therapeutic, preventive value. The national trial is being coordinated by Johns Hopkins University and sponsored by the National Institutes of Health through the Department of Defense.

"With convalescent plasma therapy, we want to act prophylactically, using a product with known high-titers (concentrations) of neutralizing antibodies," said Edward Cachay, MD, an infectious disease specialist at UC San Diego Health and professor of medicine at UC San Diego School of Medicine. "We want to learn how we can prevent sickness, how we can prevent COVID patients from needed mechanical ventilation, and how we can prevent them from dying from the disease."

Before the emergence of antibiotics, CP was used to prevent and treat a host of bacterial and viral infections, including diphtheria, scarlet fever and pertussis. It was used during the 1918 influenza pandemic with reported good effect.

In general, CP treatment has proven safe, but its effectiveness has varied with disease and among individuals. Studies of CP therapies for Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS) and the 2009 H1N1 influenza showed measurable reductions of mortality (compared to placebo or no therapy), but efforts to treat Ebola virus infections during the 2014-16 outbreak in West Africa were inconclusive.

Chinese researchers treating COVID-19 patients have reported some success using CP, albeit not in randomized, controlled studies — the gold standard in clinical research. On April 13, the Food and Drug Administration (FDA) issued research guidelines for assessing CP as a potential COVID-19 treatment and the American Red Cross is currently seeking blood plasma donors who have fully recovered from novel coronavirus infections.

Plasma is the liquid portion of blood that carries blood components throughout the body, such as red and white blood cells, platelets, salts and enzymes. It also contains proteins and antibodies produced by the body's immune system to fend off invasive pathogens, such as SARS-CoV-2.

To <u>qualify as a plasma donor</u> for COVID-19 patients, donors must be at least 17 years old and weigh 110 pounds; be in good health; and have a prior, verified diagnosis of COVID-19 but are now symptom-free and fully recovered.

The UC San Diego Health clinical trial will recruit a total of 487 qualifying participants for the study. Criteria to qualify for participation include a high-risk factor, such as age or an underlying condition, like cardiovascular disease, diabetes, existing pulmonary impairment or employment as a health care worker; known exposure to SARS-CoV-2; and a negative PCR diagnostic test to show no current infection.

Testing will be conducted inside tents set up across from the emergency department at Jacobs Medical Center and the <u>Altman Clinical and Translational Research Institute (ACTRI)</u> on the La Jolla health campus. The UC Health Blood Bank is coordinating efforts with the San Diego Blood Bank. The ACTRI is providing personnel, infrastructure support and other resources for the CP trial and for other <u>COVID-19-related clinical trials</u> at UC San Diego. In addition, the ACTRI has created a COVID-19 Biobank to provide materials for research projects to diagnose or treat the disease.

In cases of infection by the novel coronavirus, it appears the human immune system begins producing antibodies to the disease five to 10 days after the initial infection. The antibodies bind to the targeted coronavirus, stopping it from latching onto new cells and beginning the production of more viral particles. Over the course of two or so weeks, the body clears out the virus, but antibodies to it (or the blueprints for making them) remain. The depth and length of subsequent immunity have not been determined.

Cachay said he thinks CP will likely be most effective in persons with early exposure to the novel coronavirus, before symptoms appear, but it will require a clinical trial to substantiate that thinking. "If we don't do this, if we just gather anecdotal evidence that isn't conclusive, then we won't be any better off when the next wave hits."

For information about participating in this trial, contact Donna Brusch, senior study research coordinator, at <u>dbrusch@health.ucsd.edu</u> or call 760-505-6649. Interested persons can also visit the study website at <u>covid-plasmastudies.com</u>, which includes an online screening process. The UC San Diego trial officially begins Monday, July 13, 2020.

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