New drug in HealthPartners Institute clinical trial could help COVID-19 patients

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Our colleagues at HealthPartners Institute began testing a drug for severe COVID-19 pneumonia this month that may prevent lung inflammation in hospitalized patients with COVID-19 after receiving fast-track investigational approval from the FDA.

The intravenous drug, called CM4620-IE and developed by San Diego, Calif.-based CalciMedica, blocks the body's production and release of molecules that cause inflammation, potentially reducing lung damage and the need for a ventilator. The drug has been proven safe and effective in patients with acute pancreatitis with below-normal levels of oxygen, and experts at the **Critical Care Research Center at Regions Hospital**, where the study is being managed, said the goal of this treatment is to improve patient outcomes for patients suffering with COVID-19 in the setting of a global pandemic.

"There is a need for a fast-acting, potent treatment for patients with severe cases of COVID-19," said **Charles Bruen, MD**, a critical care and emergency medicine physician and researcher at Regions who is leading the study. "The drug has the potential to protect the lungs against acute respiratory distress syndrome, which is the leading cause of death for patients with COVID-19."

The study will include up to 60 hospitalized patients with COVID-19 pneumonia. To be eligible, patients must have moderately low levels of blood oxygen. Patients must be hospitalized and require oxygen support but not yet to the progression of needing support from a ventilator.

Patients in the study will be randomized to either receive three four-hour infusions of the drug over the course of three days, or receive standard care without the drug. Outcomes will be measured by the drug's safety, tolerability and effectiveness. Whether the desired result has been achieved will be determined based on changes in blood oxygen, survival without needing a ventilator, time until hospital discharge, mortality at 30 and 60 days, and changes in lung inflammation. All patients will be followed for 10 days or until discharge and contacted at 30 and 60 days for assessment.

"Through our critical care research program, we are equipped to incorporate research into the care of our most critical and complex patients," Critical Care Research Center director Sandi Wewerka said. "This environment allows us to quickly turn our focus to COVID-19 research to actively seek and test treatment options. We are eager to see if this particular drug can provide hope for some of our sickest patients suffering with COVID-19 and their families."

Pictured above, Charles Bruen, MD, is leading the COVID-19 clinical trial for the HealthPartners Critical Care Research Center at Regions Hospital.