COVID study examines efficacy of immune regulating drug

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Researchers at the University of Cincinnati are testing a commonly used drug, called sirolimus, to determine its safety and efficacy in treating hospitalized patients with COVID-19 pneumonia in the trial.

The research trial, called Sirolimus Treatment in Hospitalized Patients with COVID-19 Pneumonia (SCOPE), will examine the Food and Drug Administration-approved medication that is most commonly used to prevent organ rejection in patients with kidney transplants. It is also FDA-approved for the treatment of a rare lung disease, LAM.

There are several reasons why sirolimus was a logical target when researching potential treatments for COVID-19, according to Nishant Gupta, MD, associate professor in the Division of Pulmonary, Critical Care and Sleep Medicine in the Department of Internal Medicine at the UC College of Medicine and the principal investigator of the study. Sirolimus has been shown to inhibit the replication of a variety of viruses, including MERS. In a randomized controlled study involving healthy volunteers, treatment with medications that act similar to sirolimus resulted in improved immune response to influenza vaccination.

"In animal models, sirolimus has been shown to regulate the immune system in a way where it augments the body's response against viral pathogens and dampens the overall immune response that is responsible for the bad outcomes in patients with COVID-19," says Gupta. "This dual action of selectively augmenting the response against viral pathogens and regulating the immune system to prevent collateral organ damage makes sirolimus a really promising treatment target for patients with COVID-19."

Gupta says UC is uniquely positioned to study this drug because of previous involvement and ongoing work with the lung disease LAM. He and his colleagues are using sirolimus on a daily basis in patients with LAM and are very familiar with the nuances of prescribing the drug and the side effects associated with it.

"In many ways, the ability to repurpose an existing drug as a potential

treatment option for COVID-19 patients is enticing for both patients and the medical community," says Gupta. "This approach provides more reassurance for patients considering participating in the study as the drug has a known safety profile that has been developed over decades of experience rather than potential unknown side effects from a new medication. And, if proven beneficial, the drug is readily available to be used widely."

The SCOPE trial began enrolling patients in May and hopes to reach a target total of 30 enrollees by fall. Adult participants are eligible to be included in the study if they have confirmed COVID-19 pneumonia and are sick enough to require hospitalization with the need for supplemental oxygen. The study is designed as a placebo controlled, double-blind trial, meaning neither the patients nor researchers will know if they are getting the study drug or placebo.

Gupta says this is a very important aspect of study design in order to reduce the potential for bias and properly assess the safety and efficacy of the study drug. Much of the current data on COVID-19 is limited by being gathered from uncontrolled studies that prevent physicians from being able to assess the true treatment benefits of a drug.

"If this study shows positive results, we are committed and prepared to launch a bigger trial in time for the anticipated second wave of COVID-19 in the winter," says Gupta. "Out of the multiple drugs being tested for COVID-19 currently, personally I am most excited about working with sirolimus. By intervening relatively early in the disease course, we hope to be able to prevent patients from progressing to advanced respiratory failure where they need to be placed on a ventilator. We are hopeful that this approach can make a meaningful impact in the lives of patients infected with COVID-19."

The SCOPE trial is an investigator-initiated project funded by a pilot

grant from the University of Cincinnati College of Medicine. Assisting Gupta in the research are co-investigators Frank McCormack, MD; Duncan Hite, MD, and Kristin Hudock, MD, all in the Division of Pulmonary, Critical Care and Sleep Medicine. Also providing assistance are researchers Nusrat Harun, Ph.D.; Maurizio Macaluso, MD; Rebecca Ingledue, Alexandria Davis and Susan McMahan. The study is currently recruiting subjects at the University of Cincinnati Medical Center as well as UC Health West Chester Hospital. Loyola University in Chicago is in the process of being added as an additional site to help with patient recruitment.

Provided by University of Cincinnati