UC San Diego Health launches clinical trial to assess antiviral drug for COVID-19

March 24 2020

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Physician-scientists at four University of California Health medical centers—UC San Diego Health, UC San Francisco, UC Irvine Health and UC Davis Health—have begun recruiting participants for a Phase II clinical trial to investigate the safety and efficacy of treating adult patients with COVID-19 with remdesivir, an antiviral drug that has

shown activity in animal models and human clinical trials of SARS-CoV, MERS-CoV, Ebola, Marburg and other viruses.

Remdesivir is not approved by the U.S. Food and Drug Administration for treatment of any infection, but is undergoing clinical trials for treatment of multiple viral diseases, including COVID-19 (SARS-CoV-2) infections.

The multicenter trial will be randomized, double-blind and placebo-controlled, with the capacity to enroll in up to 75 sites globally. The UC trial will begin with a small cohort of participants. All must be hospitalized patients with diagnosed COVID-19. All must be patients of UC San Diego Health or other participating UC Health systems.

Developed by Gilead Sciences, remdesivir belongs to a class of antiviral drugs that inhibit RNA-dependent RNA polymerase, an enzyme necessary for some RNA viruses like SARS-CoV-2 to replicate. Thus, inhibiting the enzyme may prevent viral replication in infected cells. The most commonly used antiviral drug in this class of drugs is acyclovir, used for the treatment of herpes simplex virus, chickenpox and shingles.

The study will consist of a series of two-arm comparisons between different therapeutic agents and a placebo, with interim monitoring to introduce new arms as needed and to allow for early stoppage if any agents prove ineffective or unsafe.

"Due to the evolving, fluid nature of this research and what we're learning daily about the virus and about improving treatment, the trial is designed to be adaptive, to shift investigation to the most promising avenues," said co-principal investigator Constance Benson, MD, professor of medicine at UC San Diego School of Medicine and an infectious disease specialist at UC San Diego Health.

"With this type of adaptive study design, if remdesivir proves to be safe and active, the clinical trial may be rapidly adapted to remove the requirement for a placebo arm and add a treatment arm that includes other promising antiviral or other investigational drug to compare with the activity of remdesivir."

Dan Sweeney, MD, associate clinical professor in the Division of Pulmonary, Critical Care and Sleep Medicine at UC San Diego School of Medicine, is co-principal investigator of UC San Diego-based trial.

The trial is projected to run to April 1, 2023 and will ultimately involve an estimated total of 440 participants. It is sponsored by the National Institute of Allergy and Infectious Disease, part of the National Institutes of Health (NIH).

Provided by University of California - San Diego

Citation: UC San Diego Health launches clinical trial to assess antiviral drug for COVID-19 (2020, March 24) retrieved 27 April 2024 from https://medicalxpress.com/news/2020-03-uc-san-diego-health-clinical.html