UC/UC Health COVID-19 Clinical Trials

Study Name	Investigator	Sponsor	Description	Study Contact
CCR	Hudock	College of Medicine	COVID-19 Observational Study with sample and data collection to provide a mechanism to collect medical record data and specimens. (peripheral blood, sputum, nasal swab, oropharyngeal swab, stool, mini bronchoalveolar lavage (BAL), remnant BAL and tissue specimens including post- mortem biopsies) that will provide insights into the pathophysiology of a novel infectious agent, and aid in the development of new diagnostic tools and treatment strategies for patients with COVID-19.	Kristin Hudock: <u>hudockkn@ucmail.uc.edu</u> Michelle Saemann: <u>saemanmd@ucmail.uc.edu</u> 513-584-2245
Inpatient Convalescent Plasma	Huaman Joo	Mayo Clinic Expanded Access Protocol	This expanded access program will provide access to investigational convalescent plasma for patients in acute care facilities infected with SARS-CoV-2 who have severe or life-threatening COVID-19, or who are judged by a healthcare provider to be at high risk of progression to severe or life-threatening disease.	Moises Huaman Joo: <u>Moises.HuamanJoo@UCHealth.com</u> Sharon Kohrs: <u>kohrssd@ucmail.uc.edu</u> 513-584-6383
SCOPE	Gupta	Investigator Initiated	The purpose of this research study is to test the safety and efficacy of sirolimus in patients admitted to the hospital with the novel Coronavirus pneumonia (COVID-19). Sirolimus is FDA approved to prevent rejection in patients who receive kidney transplants and to treat a rare lung disease named Lymphangioleiomyomatosis (LAM). Sirolimus is not FDA-approved to treat COVID- 19.	Nishant Gupta: guptans@UCMAIL.UC.EDU Alexandria Davis: <u>Alexandria.Davis@uc.edu</u> 513-558-2187 Becky Ingledue: <u>rebecca.ingledue@uc.edu</u> 513-558-0027
DAS181	Fichtenbaum	ANSUN BioPharma	The DAS181 trial is designed using a new antiviral therapy intended to attack the virus. This experimental treatment is offered through a nebulizer treatment and sponsored by Ansun Biopharmaceuticals. The antiviral therapy will test whether we can limit and decrease the amount of infection in someone with COVID-19 pneumonia. Study participation will be offered to both adults and children (through our partners at Cincinnati Children's Hospital Medical Center). Researchers hope to enroll 82 persons in the study nationally to determine the safety and effectiveness of this treatment.	Sharon Kohrs: <u>kohrssd@ucmail.uc.edu</u> 513-584-6383

RUXCOVID- DEVENT (INCB18424- 369)	Hudock	Incyte	The purpose of this study is to evaluate the efficacy and safety of ruxolitinib in the treatment of participants with COVID-19-associated Acute Respiratory Distress Syndrome (ARDS) who require mechanical ventilation.	Alexandria Davis: <u>Alexandria.Davis@uc.edu</u> 513-558-2187
AT-03A-001	Fichtenbaum	Atea Pharmaceuticals, Inc.	The AT-03A-001 trial is a study of an investigational oral drug called AT-527 (a direct-acting antiviral drug). The objectives of this study are to evaluate the safety, tolerability and efficacy of AT-527 in older subjects (ages 45-80 years) with moderate COVID-19 and risk factors for poor outcomes (such as obesity (BMI>30), hypertension, diabetes or asthma). Eligible subjects will be randomized to blinded AT-527 (nucleotide analog) tablets or matching placebo tablets to be administered orally for 10 days.	Sharon Kohrs: <u>kohrssd@ucmail.uc.edu</u> 513-584-6383
Losartan	Benoit	The Gates Foundation	We are asking you to take part in this research study because you have either tested positive for COVID-19 (novel coronavirus), and you are in the hospital for care. The virus COVID-19 uses a specific protein on the surface of your cells to enter the cell. This protein is important to protect your lung from circulating hormones. COVID-19 blocks this protein and damages your lungs. In this study, we want to see if giving you a study drug (called Losartan) that can block this lung damaging hormone helps reduce problems with breathing while you recover from COVID-19. Losartan is approved by the U.S. Food and Drug Administration (FDA) to treat high blood pressure and diabetic kidney disease in patients with type 2 diabetes and high blood pressure. Losartan has not been approved to treat COVID-19 or its symptoms. The use of this drug in this study is considered experimental.	Abigail Vollmer: <u>vollmeal@ucmail.uc.edu</u> 513-584-0477
CSSC-001	Huaman Joo	Johns Hopkins Medical Institutions	This study is designed to test whether giving plasma containing antibodies to patients infected with the SARS-CoV-2 virus will prevent illness or lessen the severity of illness in people who are at high risk of developing COVID-19 after getting exposed to someone who is infected. We have collected plasma from people who have high levels of these antibodies because they have recovered from COVID-19. We will study two groups of people who have had recent exposure to a person with COVID-19. One group with receive high-antibody plasma through a vein while the other group (called the control group) will receive regular plasma through a vein. We want to see if the antibody-containing plasma helps prevent COVID-19 illness or lessens its severity.	Sharon Kohrs: <u>kohrssd@ucmail.uc.edu</u> 513-584-6383
CSSC-004	Huaman Joo	Johns Hopkins Medical Institutions	This study is designed to test whether administration of plasma containing antibodies to people infected with the SARS-CoV-2 virus is able to prevent disease progression or lessen the severity of disease. We have collected plasma from people who have high levels of these antibodies because they have recovered from COVID-19. We will transfuse this high-antibody plasma into one group of infected people, and transfuse the other group of people with regular plasma that does not contain high levels of antibodies to COVID-19. We want to see if the COVID-19 antibody-containing plasma helps prevent the progression of infection or lessens the severity of current symptoms.	Sharon Kohrs: <u>kohrssd@ucmail.uc.edu</u> 513-584-6383