

Researchers launch vital COVID-19 clinical trials

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Researchers from Intermountain Healthcare and University of Utah Health in Salt Lake City have launched two vital clinical trials to test the effectiveness and safety of two drugs—hydroxychloroquine (HCQ) and azithromycin—to treat patients with COVID-19.

Researchers from the two [health systems](#) plan to enroll nearly 2,300 patients who are COVID-19 positive or suspected of being positive for the virus.

"Results from these studies will help us to understand the value of hydroxychloroquine (HCQ) in treatment of COVID-19 as we seek ways to fight the virus effectively and reduce the human cost of this pandemic," said Samuel Brown, MD, principal investigator of one of the studies and a critical care researcher at Intermountain Healthcare.

Hydroxychloroquine, an anti-malarial drug typically used to treat some [autoimmune diseases](#), and azithromycin, an antibiotic typically used for sinusitis or pneumonia, have been suggested as potential treatments for COVID-19, but whether they actually help is unknown.

In addition, the drugs can cause significant side-effects. In some cases, hydroxychloroquine has increased the levels of a different virus present in the blood or caused problems with heart rhythm. Further, a surge in interest in hydroxychloroquine has left patients who take the drug to manage ongoing chronic illnesses at risk of losing access to their regular course of treatment.

"Because COVID-19 is a new disease, we're all starting from scratch," said Adam M. Spivak, MD, a principal investigator of one of the [clinical trials](#) and an infectious disease physician at University of Utah Health. "The only way to answer the key question of 'does this drug work?' is to perform an unbiased clinical trial where we study its effects."

In the first trial, patients hospitalized with suspected or confirmed COVID-19 will be given either hydroxychloroquine or azithromycin to determine whether either drug affects the severity of COVID-19 and saves lives.

Researchers plan to enroll 300 patients in the clinical trial from across all Intermountain Healthcare hospitals and University of Utah Health hospitals that are treating COVID-19 patients.

"The main question we're looking to answer in this trial is, does hydroxychloroquine improve the severity of illness and save lives for patients hospitalized with COVID-19?" said Dr. Brown.

In the second set of trials, patients with confirmed COVID-19 who are being treated as outpatients will be given hydroxychloroquine or azithromycin to determine if either drug can prevent hospitalization. The trials will also determine whether hydroxychloroquine impacts viral shedding and prevents infection of household contacts as compared to placebo.

For these outpatient trials, researchers will enroll 2,000 patients across Utah from all Intermountain Healthcare and University of Utah Health System hospitals that are treating COVID-19 patients. Patients will receive treatment and be monitored via telehealth.

Brandon Webb, MD, a principal investigator of the outpatient trial and an infectious diseases physician at Intermountain Healthcare, said there's significant global interest in both clinical trials.

"There's worldwide interest in these drugs, but the available clinical data have not yet shown any benefit," he added. "These clinical trials allow us to protect the safety of patients but also answer the really important question of benefit versus harm."

Clinical trials typically take months or years to launch. Researchers at Intermountain Healthcare, University of Utah Health, the Utah Department of Health, and the Utah Medical Association were able to launch these COVID-19 clinical trials in two weeks.

"Everyone on our research team has been working 18-hour days to make this happen," said Dr. Brown. "We've been able to be nimble and flexible while still meeting the rigorous standards of a clinical trial because the need for this knowledge is so great. We applaud all of these organizations for working collaboratively to make these clinical trials a reality and to do the right thing for our patients."

Researchers acknowledge there may be pressure on clinicians to use hydroxychloroquine for COVID-19 patients outside of a clinical trial. While it may feel reassuring to prescribe this medication in the midst of a pandemic, it may be counter-productive or even harmful until physicians better understand their impact, they say.

Two weeks ago, research leaders at Intermountain Healthcare and University of Utah Health agreed to work together to help solve this problem.

"Although some providers will choose to prescribe [hydroxychloroquine](#) to their patients, Intermountain Healthcare, University of Utah Health, the Utah Department of Health, and the UMA recognize the safest way to use this medication to treat COVID-19 is within the framework of clinical trials," said Raj Srivastava, MD, a principal investigator of the outpatient trial and assistant vice president of research at Intermountain Healthcare.

"We believe these [trials](#) will ensure patients are provided information about potential associated risks and have consented to participate so their progress can be closely monitored by [healthcare](#) providers and research staff," added Rachel Hess, MD, MS, a principal investigator of the outpatient trial and co-director for the Center for Clinical and Translational Science at the University of Utah.

Provided by Intermountain Medical Center

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