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CORONAVIRUS IN MARYLAND

Drug touted for virus getting vetted in study

Baltimore a test site for hydroxychloroquine

BY MEREDITH COHN

A large new study led in Baltimore by the University of Maryland aims to show that a malaria drug repeatedly promoted by President Donald Trump for the coronavirus without much evidence does help stem infections.

People in Maryland and at least a half-dozen other states who have been exposed to the virus began taking hydroxychloroquine this week, and researchers will monitor them to see whether the drug either prevents the respiratory infection or lessens the severity of the symptoms if they do get sick.

"The hope is that we find it works as prevention," said Dr. Miriam K. Laufer, principal investigator in Baltimore for the study. "But I'd be pleased if it works to decrease the severity of illness or the duration of infection."

The drug has been used for decades to treat malaria and autoimmune diseases such as lupus and is considered safe in lower doses in many people, said Laufer, a hydroxychloroquine expert in the University of Maryland School of Medicine's Center for Vaccine Development and Global Health.

It has shown mixed results in smaller studies, and she and others launched this See **DRUG**, page 10

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trial hoping it could help stem the spread of the COVID-19 illness by preventing the virus from infecting human cells.

But doctors and researchers have become frustrated by reports of people heeding Trump's advice and hoarding the drug so that it's not available for those who use it for other diseases. They also are alarmed, Laufer said, because people may be self-dosing a drug that can be toxic.

Some studies have been halted after sick COVID-19 patients developed heart problems and other troubles. The drug can be particularly dangerous for those with preexisting heart issues. Other studies weren't designed to prove that the drug was responsible for improvements because they didn't have a "control group" with patients taking placebos so researchers could compare patient outcomes.

The use of hydroxychloroquine has prompted the American Heart Association, American College of Cardiology and Heart Rhythm Society to jointly warn doctors of serious potential complications from the drug and an antibiotic called azithromycin.

"The urgency of COVID-19 must not diminish the scientific rigor with which we approach COVID-19 treatment," said Dr. Robert A. Harrington, heart association president, in a statement. "While these medications may work against COVID-19 individually or in combination, we recommend caution with these medications for patients with existing cardiovascular disease."

Laufer said this study, being led nationally by the University of Washington and sponsored by the Bill and Melinda Gates Foundation, is testing the drug on carefully screened healthy people because it mixes badly with some medications and can cause irregular heartbeats in people who are severely sick or have serious underlying



BEN MARGOT/AP

President Trump has been promoting the malaria drug not yet officially approved for fighting the new coronavirus, even though scientists say more testing is needed.

health conditions, particularly if the doses are too high.

Results of this trial, which aims to enroll 2,000 people, won't be available for a couple of months, and if hydroxychloroquine is shown safe and effective, then it could become part of an arsenal of treatment options when people are exposed to the coronavirus.

There are no specific therapies now. But the Maryland trial is one of dozens underway in the United States and hundreds across the globe seeking treatments, cures or vaccines for the coronavirus.

Johns Hopkins University researchers, for example, are conducting a large study of blood plasma from recovered COVID-19 patients that could be used to treat or prevent infections in others. Saint Agnes Hospital also is enrolling participants in a nationwide plasma study through the American Red Cross.

Maryland and Hopkins researchers also are working on vaccines for the virus.

Doctors at Maryland recently began another trial involving a drug once tested

for treatment of the Ebola virus called remdesivir. It appeared to be among the most promising when researchers began reviewing existing drugs for leads on coronavirus treatments, said Dr. Karen Kotloff, principal investigator on the trial in Baltimore.

This study is being conducted through the Maryland medical school's Vaccine Treatment and Evaluation Unit, which is funded by the National Institute of Allergy and Infectious Diseases and used as a ready resource for evaluating promising infectious disease treatments and vaccines. Several other universities with similar units are participating.

The trial already has enrolled 800 people with moderate to severe cases of COVID-19, and half have been given the drug. Researchers will be looking to see whether those patients improve more than those who didn't get remdesivir.

"We hopefully will have a drug that we know works," Kotloff said. "If it doesn't work, then we will have a drug we know wouldn't be useful in this circumstance."

She said showing drugs don't work tells doctors not to turn to them when nothing else helps under so-called compassionate use, in which federal regulators allow use of unapproved drugs in a last-ditch effort to prevent death.

Kotloff said remdesivir has been used in this way and some people improved, but doctors couldn't be sure it was because of the drug.

Researchers think remdesivir works by preventing the virus from replicating its genetic information within human cells, part of the process of spreading infection inside a person.

"There are no guarantees," Kotloff said. "But if it works, we'll know mid- to late May. And depending on which crystal ball you're looking at, it could go rapidly through FDA licensure and be helpful to people still getting serious infections in this wave."