Can Hydroxychloroquine Prevent or Cure COVID-19?

Drugs used for decades to treat malaria may help people with the new coronavirus, but clinical trials are needed.

March 23, 2020 By Liz Highleyman

For the latest news about hydroxychloroquine and other COVID-19 treatments, see COVIDHealth.com.

Chloroquine and hydroxychloroquine (Plaquenil), two inexpensive medications long used to treat malaria, are being studied as potential therapies for the new coronavirus sweeping the globe. While early research shows they have some activity against the virus, they are not yet approved for COVID-19, and they can cause serious side effects.

The medications became the subject of political as well as scientific controversy after President Donald Trump said chloroquine was a promising approved therapy for COVID-19—the respiratory disease caused by the new virus—at his March 19 daily media briefing. Two days later, he touted a combination of hydroxychloroquine and the antibiotic azithromycin on Twitter.

> HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine. The FDA has moved mountains - Thank You! Hopefully they will BOTH (H works better with A, International Journal of Antimicrobial Agents).....
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> — Donald J. Trump (@realDonaldTrump) March 21, 2020

National Institute of Allergy and Infectious Diseases director Anthony Fauci, MD, and Food and Drug Administration (FDA) commissioner Stephen Hahn, MD, countered that neither drug is currently approved for COVID-19, and clinical trials still must be done to confirm the drugs' safety and effectiveness.

While Trump suggested chloroquine is a "game changer," Fauci called the evidence to date "anecdotal," and Hahn cautioned, "We may have the right drug, but it may not be in the appropriate dosage form right now, and it may do more harm than good."

As cases of COVID-19 continue to rise worldwide, researchers are testing dozens of treatment candidates, many of which are currently approved for other conditions. Several hundred clinical trials of potential therapies are now underway.

As recently reported, the HIV antiretroviral pill Kaletra (lopinavir/ritonavir) proved no more effective than standard supportive care in one of the first clinical trials of the drug, and the company that manufactures another HIV protease inhibitor, Prezista (darunavir), warned that it is unlikely the drug will have significant activity against the coronavirus.

Chloroquine is a synthetic version of quinine, the active compound in cinchona tree bark, which has a long tradition of medicinal use. Developed by scientists at Bayer in 1934, it was initially considered too toxic, but a decade later it was widely adopted for malaria treatment and prevention.

Hydroxychloroquine has similar activity but causes fewer side effects. In addition to malaria, it is also FDA-approved for the treatment of the autoimmune diseases lupus and rheumatoid arthritis. It is also sometimes used off-label to treat Lyme disease.

Although it is not clear exactly how chloroquine and hydroxychloroquine work, they have been shown to have activity in the laboratory against the new coronavirus (officially known as SARS-CoV-2) and the related coronavirus that caused the 2003 SARS outbreak.

An early study in China, where the current pandemic emerged in December, showed that COVID-19 patients treated with chloroquine appeared to fare better than untreated people, although Chinese authorities cautioned that the drug can cause potentially fatal side effects. Both chloroquine and hydroxychloroquine are currently being used to treat hospitalized patients with severe COVID-19 in several countries, including the United States.

The idea of chloroquine as a treatment for the new coronavirus recently went viral when Tesla founder Elon Musk tweeted a link to a compilation of prior research about the drug. Reports by Fox News and other media might have brought it to Trump's attention.

The latest burst of excitement arose from a small French study of 42 COVID-19 patients who were either asymptomatic or had upper or lower respiratory tract symptoms. Twenty-six of them were treated with hydroxychloroquine; six of them also received azithromycin—the combination touted by Trump. The study was not randomized, meaning the treated and untreated participants might

have differed in other respects.

Furthermore, the researchers excluded six treated patients who were transferred to intensive care, died, left the hospital or stopped treatment because of side effects. Under normal circumstances, this would be considered poor research methodology, but the study authors were focused on treating people, not getting clean data.

The 20 treated patients who were followed for at least six days had lower SARS-CoV-2 viral load in nose and throat swab samples than untreated people. At day 6, 100% of the people who received the combination and 57% of those who received hydroxychloroquine alone were cured, compared with just 13% in the untreated group, the researchers reported. They did not discuss treatment side effects.

These results notwithstanding, the Centers for Disease Control and Prevention cautions, "There are no currently available data from randomized clinical trials to inform clinical guidance on the use, dosing or duration of hydroxychloroquine for prophylaxis or treatment of SARS-CoV-2 infection."

Numerous clinical trials of chloroquine or hydroxychloroquine for COVID-19 treatment are underway or will be enrolling soon. The World Health Organization's large international SOLIDARITY trial will look at these two drugs along with Kaletra (alone or in combination with interferon-beta) and Gilead Sciences' experimental antiviral remdesivir.

Researchers from the University of Minnesota will evaluate hydroxychloroquine in around 1,500 people who have been exposed to the coronavirus within the past three days but do not yet have symptoms. An effective and well-tolerated preventive therapy would be of great benefit for health care workers at risk of exposure (pre-exposure prophylaxis) as well as for people who have already been exposed (post-exposure prophylaxis).

In the meantime, doctors are allowed to prescribe medications approved for any indication "off-label" for other uses, or drugs may be used under a compassionate use protocol that requires providers to collect and report data to the FDA. Generic chloroquine is widely available, sometimes without a prescription, in developing countries.

Medical experts and advocates are discouraging the premature use of chloroquine and hydroxychloroquine before randomized clinical trials are conducted to prove they are safe and effective. The medications cause side effects ranging from mild gastrointestinal symptoms and temporary tinnitus to heart rhythm abnormalities, kidney impairment and eye damage, especially at high doses or with prolonged use.

While such side effects may be acceptable when treating a life-threatening disease in patients with no other options, the risk-benefit balance is different for healthy people hoping to prevent COVID-19. There have already been reports of serious toxicity in people using chloroquine for prevention without medical supervision.

Nigeria records chloroquine poisoning and price hikes after Trump endorses the drug for coronavirus treatment https://t.co/sOrqK8p7W7

— CNN Africa (@CNNAfrica) March 23, 2020

What's more, use of chloroquine and hydroxychloroquine for COVID-19 has reportedly led to shortages for people who need them for currently approved indications.

"This threatens to cause a shortage of the drug for people it's actually indicated for, while putting others at risk who may get no benefits," Richard Jefferys of the Treatment Action Group told POZ.

Fortunately, Bayer (which manufactures chloroquine under the brand name Resochin) and Mylan, Novartis and Teva (which make generic versions of hydroxychloroquine) have ramped up production and have announced that they will donate their drugs to hospitals, researchers and the U.S. government.

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