

Anti-Malarial Drug Trump Touted Is Linked to Higher Rates of Death in VA Coronavirus Patients, Study Says

Patients treated with hydroxychloroquine and an antibiotic combination received no benefit in rates of death or in use of a ventilator

By Christopher Rowland

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{Video}

Caption: President Trump on April 21 said that he would be looking into new studies warning against using hydroxychloroquine to combat the novel coronavirus. (The Washington Post)

An anti-malarial drug President Trump has aggressively promoted to treat Covid-19 had no benefit and was linked to higher rates of death for Veterans Affairs patients hospitalized with the novel coronavirus, according to a study, raising further questions about the safety and efficacy of a treatment that has seen widespread use in the pandemic.

The study by VA and academic researchers analyzed outcomes of 368 male patients nationwide, with 97 receiving hydroxychloroquine, 113 receiving hydroxychloroquine in combination with the antibiotic azithromycin, and 158 not receiving any hydroxychloroquine.

Rates of death in the groups treated with the drugs were worse than those who did not receive the drugs, the study found. Rates of patients on ventilators were roughly equal, with no benefit demonstrated by the drugs.

More than 27 percent of patients treated with hydroxychloroquine died, and 22 percent of those treated with the combination therapy died, compared with an 11.4 percent death rate in those not treated with the drugs, the study said. The results were from an observational study of outcomes and were not part of a randomized, placebo-controlled clinical trial, which is the gold standard for testing drugs.

The study was published on the site medrxiv.org, which is a clearinghouse for academic studies on the coronavirus that have not yet been peer-reviewed or published in academic journals.

{Video}

Caption: Claims about hydroxychloroquine to treat covid-19 have gained traction despite a lack of scientific

evidence. How did this happen? (Elyse Samuels, Meg Kelly, Sarah Cahlan/The Washington Post)

“An association of increased overall mortality was identified in patients treated with hydroxychloroquine alone,” wrote the authors, who are affiliated with the University of Virginia, the University of South Carolina, and the VA system in Columbia, S.C. “These findings highlight the importance of awaiting the results of ongoing prospective, randomized, controlled studies before widespread adoption of these drugs.”

The coronavirus pandemic has overtaken the globe faster than science can respond. There are no vaccines or treatments approved to combat its spread or ease severe respiratory symptoms that have claimed over 175,000 lives worldwide.

In some cases, hope has trumped evidence in the worldwide rush to find counter-measures. Hospitals and doctors around the world have been prescribing chloroquine and hydroxychloroquine, often in combination with azithromycin, based on a belief it can help, despite a lack of sound evidence that the drugs make patients better or eliminate virus from the body.

Interest in the drugs peaked after Trump began repeatedly boosting their use in White House news conferences. He tweeted a reference to a French study in March that has since come under scrutiny for its skimpy trial size and questionable methods. In a decision that did not cite any evidence of benefit, the Food and Drug Administration issued an emergency use authorization allowing the drug to be administered in hospitals.

But the dangers of these drugs to treat certain coronavirus patients is becoming apparent, especially when hydroxychloroquine is used in combination with azithromycin. The small risk of cardiac death for patients on these drugs stems from a well-known side effect: They extend the split-second time required for the heart to recharge between beats, a condition called QT prolongation.

Citing the phenomenon, a panel of the Infectious Diseases Society of America, citing the risks, strongly advised its physician members that the combination of the drugs should be given only in a clinical trial. It cited the lack of clear evidence of any benefit. Its treatment guidelines stated the “overall certainty of evidence was very low.”

The French national agency in charge of drug safety reported that 43 patients taking

hydroxychloroquine or a combination of the drug and azithromycin suffered cardiac-related side effects and between one and four deaths. The agency said the drugs should be given only to patients who are hospitalized with covid-19, the disease the coronavirus causes. Researchers in Brazil ended a portion of a clinical trial testing high doses of chloroquine in covid-19 patients after they developed heart problems and suffered higher mortality.

A team of researchers at New York University's Langone Medical Center found that, out of 84 patients treated with the combination of hydroxychloroquine and azithromycin, 11 percent had QT prolongation beyond 500 milliseconds—the proven danger zone for sudden cardiac death. Thirty percent of the patients overall had significant increases in their hearts' QT intervals.

Lior Jankelson, a lead researcher on the Langone study, said the danger makes it highly inadvisable for people to take the drug as a prevention or without a positive coronavirus test, which has reportedly been happening around the world.

“If the patient is not proven to be sick, then I think there is no question that the risk associated with this therapy is not reasonable,” he said in an interview.

“This is a really extreme situation ... where you have hundreds of thousands, if not more, of people taking a known combination that prolongs the QT interval in a generally high-risk situation,” he said.

In hospitals, the way to manage the risk of fatal side effects is with electrocardiogram monitoring, according to specialists. But even advanced ECG screening may not reduce the risk.

The NYU Langone study showed that existing QT prolongation did not predict a subsequent QT increase from use of the drugs. Renal failure was a greater risk factor—indicating the sickest patients are at the greatest risk of dangerous side effects from the drugs.

Link

<https://www.washingtonpost.com/business/2020/04/21/anti-malarial-drug-trump-touted-is-linked-higher-rates-death-va-coronavirus-patients-study-says/>