

Experts Warning: Don't Use Off-Label Medications for COVID-19 Treatment



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An early study indicated an antimalarial drug might be effective in treating COVID-19, but experts say more research is needed, and people shouldn't use off-label medications on their own. Kay Nietfeld/picture alliance via Getty Images

FDA Notice

The FDA

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have removed the Emergency Use Authorization (EUA) for hydroxychloroquine and chloroquine for the treatment of COVID-19. Based on a review of the latest research, the FDA determined that these drugs are not likely to be an effective treatment for COVID-19 and that the risks of using them for this purpose might outweigh any benefits.

When a study was published last week suggesting that an antimalarial and antibiotic could work together as a treatment for COVID-19, interest in these drugs skyrocketed.

This was especially true on social media, where the drug combo gained a further boost after President Donald Trump tweeted about the study.

One of the drugs is the antimalarial chloroquine — or the related hydroxychloroquine, which is used to treat inflammatory disorders like lupus and rheumatoid arthritis.

The antibiotic is azithromycin.

Experts caution that it's too early to tell whether these drugs will be a game changer in slowing the pandemic.

There are also concerns that people who try to use these medications could face serious health consequences.

Andrew Thorburn, DPhil, professor and chairman of the University of Colorado School of Medicine Department of Pharmacology, says while the new study is “encouraging,” it has “significant limitations.”

These drugs are already approved by the Food and Drug Administration (FDA) for other conditions, so some doctors in the United States have been using them to treat people with COVID-19

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But mostly in a trial and error fashion.

Thorburn says the only way to be sure whether these drugs are safe and effective for COVID-19 is with larger, better designed clinical trials.

“Even in a rapidly changing situation like this pandemic, the worst thing you can do is to just try things without knowing what it is you are doing,” Thorburn told [name removed].

A small, limited study

In the new study, doctors in France gave hydroxychloroquine to 26 people with COVID-19.

Six of the participants dropped out of the study early when they were transferred to the intensive care unit (ICU) or refused treatment.

Six study participants taking the antimalarial drug also received azithromycin.

The doctors also monitored a group of 16 control participants who received routine medical care but neither of the drugs.

After 5 days of treatment, the researchers reported that all six participants taking both drugs were free of SARS-CoV-2, the virus that causes COVID-19.

Eight of the 14 participants who took only hydroxychloroquine were free of the virus after 6 days of treatment. Two of the 16 control participants no longer had an infection after 6 days.

The study's flaws

The study was published March 20 in the International Journal of Antimicrobial Agents.

Lindsay C. Kobayashi, PhD, an assistant professor of epidemiology at the University of Michigan School of Public Health, says the study has certain design flaws that limit the usefulness of the results.

Other researchers have voiced similar concerns.

First, participants weren't randomly assigned to receive hydroxychloroquine or usual care, which can affect results.

"There could be preexisting differences between the study groups that could have influenced their viral load at the end of the study, such as how sick they were when the study started," Kobayashi told [name removed].

Without randomization, it's difficult to know whether people who did well on the treatment got better because of the drug or because of other factors.

Second, several participants taking hydroxychloroquine dropped out of the study early, including five who tested positive for COVID-19.

Kobayashi says these participants should have been included in the statistical analysis. It also means the virus wasn't really eliminated in all the participants treated with hydroxychloroquine.

Third, Kobayashi says the authors of the study used a different definition of a negative COVID-19 test than what the Centers for Disease Control and Prevention (CDC) recommends.

"[They] used a lower threshold for testing negative, which allowed them to claim 100 percent eradication of viral load among COVID-19 patients," she said.

Larger clinical trials needed

This doesn't mean the new study isn't useful, just that more research is needed.

"[The study] is encouraging enough that one would want to investigate further, such as with more rigorous and larger clinical trials," Thorburn said.

Some of these are already underway, including one being run by researchers at the University of Minnesota as well as studies in the United Kingdom and Norway.

But we'll have to wait until the results from these studies are available to know whether the drugs work, and if so, at what dose and for which patients.

And whether they're safe.

Serious health consequences

Both chloroquine and hydroxychloroquine can have serious side effects, such as irregular heartbeat, mood changes, or convulsions.

Azithromycin can also have serious side effects, including the risk of potentially fatal heart rhythms

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"All drugs have side effects," Thorburn said. "Sometimes those are dangerous and can even make things worse."

There are other dangers to overhyping the results of studies like this new one.

People who have access to one of these drugs may be tempted to self-treat if they think they have COVID-19.

Chloroquine poisonings have already been reported in Nigeria.

Because of the risk of serious side effects, these drugs should only be taken under a doctor's supervision.

And because around 80 percent

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of people recover from COVID-19 without needing special treatment, taking unprescribed medications could be riskier than waiting it out.

Also, some people may try other chemicals that they think are the same as these drugs.

U.S. News reports that a man from Arizona died after taking chloroquine phosphate, an additive used to clean fish tanks. His wife, who also took the substance, is in critical condition.

And then there's the toilet paper effect.

There are already concerns that if people start hoarding hydroxychloroquine, those who already use it to treat their lupus or rheumatoid arthritis won't be able to get the drug.

A similar high demand has occurred for the antiviral remdesivir, which is also being investigated for its use against COVID-19. So much so that manufacturer Gilead had to suspend emergency access to the drug.

Famotidine, the active compound in the over-the-counter heartburn drug Pepcid, is also trending online after a report

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that doctors in New York City are testing it as a potential treatment for people with severe COVID-19.

In the study, doctors are administering high doses of famotidine to patients in critical care, some on ventilators. The study results are not yet available.

Doctors also caution against patients self-treating because high doses of this drug can cause heart problems in some people.

Kobayashi says from a public health and medical ethics perspective, reports of chloroquine poisonings and hoarding of this and other drugs is "extremely concerning."

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