Inexpensive Steroid Is First Drug Shown to Reduce COVID-19 Deaths

Dexamethasone reduced mortality by up to a third among severely ill patients who needed supplemental oxygen or ventilators.

June 17, 2020 By Liz Highleyman

Low-dose dexamethasone, a widely used and inexpensive steroid, is the first medication shown to reduce the risk of death for hospitalized patients with severe respiratory complications related to COVID-19, according to researchers at the University of Oxford.

These findings come from the RECOVERY (Randomised Evaluation of COVID-19 Therapy) trial, which is comparing multiple different therapies for people with advanced COVID-19, the disease caused by the new coronavirus (officially known as SARS-CoV-2).

> Oxford study shows low-cost COVID-19 drug improves survival rate in hospitalised patients with severe respiratory complications. Dexamethasone is the first treatment demonstrated to reduce #COVID19 mortality & is already widely available around the world: https://t.co/HHGV9KlcnV pic.twitter.com/m6GYQTmrv0
>
> — University of Oxford (@UniofOxford) June 16, 2020

The study results were announced in a University of Oxford press release. They have not yet been peer reviewed or published in a medical journal.

“Dexamethasone is the first drug to be shown to improve survival in COVID-19,” one of the study’s chief investigators, Peter Horby, MD, PhD, a professor of emerging infectious diseases at the

University of Oxford, said in a statement. “The survival benefit is clear and large in those patients who are sick enough to require oxygen treatment, so dexamethasone should now become standard of care in these patients. Dexamethasone is inexpensive, on the shelf and can be used immediately to save lives worldwide.”

Severe lung damage and other manifestations of COVID-19 are attributable in part to the coronavirus itself and in part to the immune system’s response to it. Some people develop an immune overreaction known as a cytokine storm that can cause excessive inflammation and severe organ damage.

Researchers are studying a variety of therapies to calm inflammation in COVID-19 patients, including steroids such as dexamethasone and cytokine inhibitors such as Actemra (tocilizumab)—used to manage cytokine storms in people receiving cancer immunotherapy—and Olumiant (baricitinib). But some experts have urged caution, as steroids have been linked to worse outcomes among people with SARS or MERS, diseases caused by related coronaviruses. Other medications, such as remdesivir, are antivirals aimed at stopping SARS-CoV-2 replication.

The RECOVERY trial has enrolled more than 11,500 COVID-19 patients at over 175 National Health Service hospitals in the United Kingdom. In addition to low-dose dexamethasone (a glucocorticoid used to treat rheumatoid arthritis, asthma, certain cancers and other conditions), the study is also evaluating the HIV antiretroviral medication Kaletra (lopinavir/ritonavir), hydroxychloroquine (a drug touted by President Trump), azithromycin (a commonly used antibiotic), Actemra and convalescent plasma (blood plasma from recovered COVID-19 patients that contains antibodies against SARS-CoV-2). Enrollment in the hydroxychloroquine arm was previously halted due to apparent lack of benefit.

A total of 2,104 study participants were randomly assigned to receive 6 milligrams of dexamethasone once daily, administered either as a pill or via IV injection. This group was compared against 4,321 people randomized to receive the usual care without any of the study drugs.

Among the participants who received the usual care, mortality rates were 41% for those who required mechanical ventilators, 25% for those who needed supplemental oxygen and 13% for those who did not require any respiratory support.

Over 28 days, dexamethasone reduced mortality by 17% overall. This was driven by a 35% reduction among patients on ventilators and a 20% reduction among those receiving supplemental oxygen alone. Participants who did not need respiratory support saw no added benefit.

The researchers calculated that use of dexamethasone could prevent one death for every eight people on ventilators or every 25 patients receiving supplemental oxygen.

While the University of Oxford press release did not report safety results, dexamethasone is generally considered safe and well tolerated. Side effects may include headache, dizziness,

insomnia, mood changes, swelling and weight gain.

After reviewing these findings, the trial's steering committee halted recruitment into the dexamethasone arm, having determined that enough people had been enrolled to establish whether the drug offers meaningful benefits.

"Since the appearance of COVID-19 six months ago, the search has been on for treatments that can improve survival, particularly in the sickest patients," said lead investigator Martin Landray, PhD, a professor of medicine and epidemiology at the University of Oxford. "COVID-19 is a global disease—it is fantastic that the first treatment demonstrated to reduce mortality is one that is instantly available and affordable worldwide."

> This is a robust finding and could meaningful affect outcomes. We're learning how to better treat advanced Covid disease and, combined with other new strategies like anticoagulation, we should see Covid mortality rates decline as long as we preserve our healthcare capacity. https://t.co/QEQotEeOz0
>
> — Scott Gottlieb, MD (@ScottGottliebMD) June 16, 2020

Some experts not involved with the study agreed that the results appear promising.

"This is a robust finding and could meaningful[ly] affect outcomes," former Food and Drug Administration commissioner Scott Gottlieb, MD, now with the American Enterprise Institute, said in a tweet.

> It will be great news if dexamethasone, a cheap steroid, really does cut deaths by 1/3 in ventilated patients with COVID19, but after all the retractions and walk backs, it is unacceptable to tout study results by press release

without releasing the paper. https://t.co/ZP5GVMUCW3

— Atul Gawande (@Atul_Gawande) June 16, 2020

But author Atul Gawande, MD, MPH, a surgeon at Brigham and Women's Hospital in Boston, sounded a note of caution about touting study results in a press release in light of recent walk-backs stemming from the unprecedented speed and widespread dissemination of COVID-19 research prior to the usual peer review process.

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