

Multiple studies confirm steroids can fight severe COVID-19

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A slew of "gold standard" clinical trials offer new hope for patients battling severe COVID-19: cheap, common drugs known as corticosteroids appear to cut the death rate by a third.

Publication of new data on treatment with corticosteroids such as hydrocortisone or dexamethasone "represents an important step forward in the treatment of patients with COVID-19," said Dr. Hallie Prescott of the University of Michigan, Ann Arbor, and Dr. Todd Rice, of Vanderbilt University in Nashville, Tenn.

They wrote an editorial accompanying four studies on corticosteroids and COVID-19, all published online Sept. 2 in the *Journal of the American Medical Association (JAMA)*.

One of the studies was a "meta-analysis"—a review of data looking at the combined results of seven different clinical trials. Those trials involved more than 1,700 critically ill COVID-19 patients treated at medical centers in 12 countries.

The data showed that the use of corticosteroids in the care of these patients cut the death rate (after one month of treatment) by about one-third, according to researchers led by Jonathan Sterne, of the University of Bristol in the United Kingdom. This finding was true for patients requiring mechanical ventilation as well as those who required supplemental oxygen but not a ventilator, the research team added.

Overall, "these trial results from diverse clinical and geographical settings suggest that in the absence of compelling contraindications, a corticosteroid regimen should be a component of standard care for critically ill patients with COVID-19," Sterne's group concluded.

Quieting the storm

How might corticosteroids—which have been around for decades—help save lives threatened by COVID-19? As Prescott and Rice explained, these drugs work to counter the runaway inflammatory response—the so-called "cytokine storm"—that can drive late-stage COVID-19 and overwhelm patients' defenses.

In addition, many patients treated for COVID-19 in the intensive care unit (ICU) require ventilators to breathe because they develop a condition known as acute respiratory distress syndrome (ARDS). ARDS is often seen in advanced cases of pneumonia and other illnesses, and can easily prove fatal.

But Prescott and Rice noted that, as early as 1967, experts noted that "corticosteroids appeared to have value in the treatment of patients" with severe pneumonia and ARDS.

In June, the first solid evidence that the drugs might fight COVID-19 also emerged, with the publication of results from a British trial of more than 6,400 patients. That trial found that use of

dexamethasone cut the death rate by about one-third for patients on ventilators, and by about one-fifth for those requiring supplemental oxygen.

In the latest issue of *JAMA*, researchers working on three new clinical trials found preliminary results indicating that corticosteroids would help against COVID-19.

One trial from Brazil, involving 299 patients treated in ICUs, found that adding dexamethasone to treatment "resulted in a statistically significant increase in the number of ventilator-free days" over 28 days of treatment. Two other trials—one from France and the other including American patients—also suggested real improvement from the use of corticosteroids.

The 'clearest answer'

The U.S. trial involved 403 COVID-19 patients treated in an ICU between March and June. It found a 93% probability that adding intravenous hydrocortisone to patients' treatment would end in better outcomes.

"This gives physicians like me, who treat the sickest of the sick, hope. We are beginning to get a handle on the deadly side of this disease," study co-author Dr. Bryan McVerry said in a University of Pittsburgh news release. He's an associate professor of pulmonology, allergy and critical care medicine at Pitt.

Study lead author Dr. Derek Angus, who directs the department of critical care medicine at Pitt, added that "it is relatively rare in medicine that you find drugs where the evidence of their effectiveness in saving lives is so consistent. This is, in many respects, the single clearest answer we've had so far on how to manage terribly ill COVID-19 patients. People on ventilators or oxygen and under intensive care should definitely be given corticosteroids."

However, publication of clear evidence of benefit from the British trial in June meant that withholding corticosteroid treatment from patients in the "control" arms of the Brazilian, French and U.S. trials was no longer ethical, so each of those trials

were discontinued early.

The meta-analysis of data from seven different studies was completed, however, and shows clear benefit from corticosteroid treatment.

According to the meta-analysis, the steroid dexamethasone was used in three trials involving a total of almost 1,300 patients, and seemed to cut the death risk by 36% compared to standard care.

Hydrocortisone was employed in three trials involving a smaller number of patients (374) and cut the death risk by 31%, Sterne's group reported.

Corticosteroids can have serious side effects, but the meta-analysis revealed little difference in "serious adverse events" for patients who got the drugs versus those who did not.

Still, some questions remain. According to editorialists Prescott and Rice, those questions include: "Does inflammation rebound after cessation of corticosteroids? ... Should less severely ill or non-hospitalized patients be treated with corticosteroids? ... Should remdesivir or other potentially active therapeutics be administered with corticosteroids?"

Overall, however, the results of the new trials published online Sept. 2 in *JAMA* are encouraging, Prescott and Rice said.

"The COVID-19 pandemic has brought fear and a sea of change to the world," they said. "These studies provide evidence and some hope that an effective, inexpensive and safe treatment has been identified."

More information: *JAMA* (2020). DOI: [10.1001/jama.2020.17021](https://doi.org/10.1001/jama.2020.17021)

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