

Rheumatoid arthritis drug combined with standard of care may help reduce mortality for hospitalized COVID-19 patients

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Hospitalized patients with COVID-19 who received the rheumatoid arthritis drug baricitinib, in combination with the standard of care including corticosteroids, died less often than those receiving only the standard of care, according to a study released this week in *The Lancet Respiratory Medicine*.

The study, led by principal investigators E. Wesley Ely, MD, MPH, Grant Liddle Professor of Medicine at Vanderbilt University Medical Center, and Vince Marconi, MD, of Emory University, included 1,525 [hospitalized patients](#) on supplemental oxygen from 101 centers across 12 countries in Asia, Europe, North America and South America.

Ely and Marconi received no [financial compensation](#) for their work on the study, which was funded by Eli Lilly and Company, the company that makes baricitinib, a medication known for its anti-inflammatory properties.

Patients in the COV-BARRIER trial were randomly assigned to receive baricitinib vs. placebo once a day for up to 14 days in addition to the standard of care, which included the medications dexamethasone and remdesivir.

The COV-BARRIER investigation discovered that baricitinib reduces 28-day and 60-day mortality by 5% as compared to placebo.

"Hospitalized patients with the SARS-CoV-2 infection (which causes COVID-19), often develop an intense hyperinflammatory state that can lead to dysfunction of multiple organs, including acute respiratory distress syndrome, septic shock and death," Ely said. "Despite treatment advances with remdesivir, dexamethasone and tocilizumab, reducing mortality among hospitalized patients remains a crucial unmet need.

"It is increasingly evident that treatment with baricitinib may help prevent death in some of the most critically ill COVID-19 patients, and that this class of medications represents an important treatment advance for this vulnerable group of patients in the constantly evolving pandemic," Ely said.

Baricitinib is an inhibitor of Janus kinases (JAK) 1 and 2, which "calms down your immune system," Ely said. "A huge computer analysis was done early in the pandemic, trying to figure out what drugs were the best to repurpose for COVID anti-viral effects," Ely said. "Anti-inflammatory effects are also important for sicker, hospitalized patients. JAK inhibitors selectively hit signaling via the JAK receptors, blocking transduction pathways that lead to inflammation," he said. "Drugs like baricitinib stop multiple pathways of the inflammatory cascade to hold down the inflammation that COVID would usually start."

Ely added that the COV-BARRIER data show that the sicker patients were at the time of enrollment, the greater the reduction in mortality.

Provided by Vanderbilt University Medical Center

Data from a COV-BARRIER addendum, which included hospitalized patients with COVID-19 on mechanical ventilation and ECMO (extracorporeal membrane oxygenation) at the time of enrollment, showed an even greater improvement in survival in the group given baricitinib, Ely said.

One surprising finding in the *Lancet* study is that although the drug reduces death, some patients still progress in their severity of illness.

"When COVID hits your body and the train is leaving the station, we did not find that this medication stopped the progress of the disease process entirely," Ely said. "If you were already sick, you continued to get a little sicker. The train keeps going a little bit, but adding baricitinib keeps you from going over the cliff into death."

Baricitinib was identified in February 2020 as a potential intervention for the treatment of COVID-19. The FDA granted Emergency Use Authorization (EUA) to the drug in November 2020, to be given in combination with the drug remdesivir, then amended the EUA later to allow baricitinib to be given with or without remdesivir.

Lilly is donating COVID-19 therapies to Direct Relief, enabling the humanitarian organization to provide COVID-19 therapies at no cost to low- and lower-middle-income countries most heavily impacted by the pandemic. In May, Lilly announced an initial donation of 400,000 baricitinib tablets to the Indian government for eligible hospitalized COVID-19 [patients](#) in India.

More information: Vincent C Marconi et al, Efficacy and safety of baricitinib for the treatment of hospitalised adults with COVID-19 (COV-BARRIER): a randomised, double-blind, parallel-group, placebo-controlled phase 3 trial, *The Lancet Respiratory Medicine* (2021).

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