

# USC Keck Medicine Launches Clinical Trial to Study Baricitinib, an Anti-Inflammatory, as COVID-19



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**Keck Medicine of USC physicians are launching a clinical trial to evaluate the efficacy and safety of baricitinib, an anti-inflammatory drug approved by the Food and Drug Administration to treat rheumatoid arthritis, as a possible treatment for patients with moderate to severe COVID-19.**

Certain COVID-19 patients face a potential risk of a “cytokine storm.” Cytokines are small proteins in the body that help the immune system battle infection. However, having a large amount released into the body all at once can result in excess inflammation that causes tissue damage and organ failure. The investigators hypothesize that the use of baricitinib may reduce inflammation and slow down the disease progress—perhaps even halting the need for a ventilator to save lives. Baricitinib represents one of several anti-inflammatory drugs being evaluated in COVID-19 patients.

## The Context

Physicians are launching this trial to evaluate the efficacy and safety of baricitinib, an anti-inflammatory drug approved by the Food and Drug Administration to treat rheumatoid arthritis, as a possible treatment for patients with moderate to severe COVID-19. Michael Dube, MD, an infectious disease specialist at Keck Medicine and interim chief of the division of infectious diseases at the Keck School of Medicine of USC commented, “We are learning that in some COVID-19 cases, inflammation might be driving the need for

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intubation and causing poor outcomes. Dr. Dube will lead the trial along with Heinz-Josef Lenz, MD, associate director of clinical research of the USC Norris Comprehensive Cancer Center, who serves as the principal investigator.

### Sponsor

Eli Lilly is paying for this study. They are the makers of Baricitinib

### The Study

This clinical trial is a double-blind, randomized controlled study. Half of the patients will receive baricitinib in the form of a daily tablet medication and other half will receive a placebo. Investigators seek to enroll 144 patients from Keck Hospital of USC, USC Verdugo Hills Hospital, and Los Angeles County and USC Medical Center.

The participants will include patients who exhibit COVID-19 symptoms but not have reached the stage where they have to be intubated. Patients with a heightened risk factor of the virus, such as those 60 or older, with a chronic heart or lung condition, obesity, hypertension, or diabetes are also eligible.

### Search for Biomarkers

The two primary investigators will also collaborate with [Bodour Salhia](#), PhD, an assistant professor of translational genomics at the Keck School on related but different research. Salhia will collect blood samples

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drawn during the study to look for molecular biomarkers to identify COVID-19 patients who are at a high-risk for developing severe outcomes. Salhia will utilize a liquid biopsy methodology she has developed for ongoing cancer research. She reports “Finding such biomarkers will lead to better management and protection of high-risk individuals.”

**Lead Research/Investigator**

**Michael Dube**, MD, an infectious disease specialist at Keck Medicine and interim chief of the division of infectious diseases at the Keck School of Medicine

**Heinz-Josef Lenz**, MD, associate director of clinical research of the USC Norris Comprehensive Cancer Center,

**Bodour Salhia**, PhD, assistant professor of translational genomics at the Keck School



Source: EurekaAlert!

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