

Clinical trial for drug to treat severe COVID-19 patients

April 24 2020, by Brita Belli



Credit: CC0 Public Domain

Yale researchers will begin a clinical trial at Yale-New Haven Hospital to test the effectiveness of a drug called ibudilast (MN-166) for treating acute respiratory distress syndrome (ARDS), a life-threatening lung condition developed by some of the most seriously ill COVID-19 patients. The researchers are part of Yale's Advanced Therapies Group,

which was formed in response to the pandemic and is identifying and advancing possible treatments for the disease.

The drug—which has been approved for years in Japan and Korea for the treatment of asthma—has shown promising results for reducing inflammation associated with ARDS in mouse models. The researchers have partnered with the California company MediciNova to launch the trial. MediciNova had been developing ibudilast as a treatment for multiple sclerosis and neuroinflammation before shifting its attention to COVID-19.

The trials will be controlled studies that test the safety and efficacy of ibudilast for use in patients with COVID-19.

The researchers anticipate FDA approval soon "to treat patients with COVID-19 pneumonia before they develop severe respiratory distress and require mechanical ventilation," said Dr. Geoffrey Chupp, professor of medicine (pulmonary), director of the Yale Center for Asthma and Airways Disease, and principal investigator of the clinical trial.

The most severely ill COVID-19 patients develop ARDS, which causes hyper-inflammation and fluid buildup in the lungs and leads to a sharp drop in oxygen levels. These patients need ventilators to support their breathing, and their prognosis for survival has been poor. The researchers hope that the drug will reduce damaging inflammation and mitigate the progression of COVID-19-related ARDS, diminish lung injury, and allow patients to recover.

"COVID-19 causes an intense inflammation reaction known as a 'cytokine storm,'" said Chupp. In patients, this presents as COVID-19-related pneumonia or ARDS.

"If you can modulate that," he said, "you can dial back the severity of the

illness."

"We have designed a placebo-controlled trial to see if blocking the effects of macrophage inhibitory factor, or MIF, can protect patients with COVID-19 from developing ARDS," said Dr. Maor Sauler, assistant professor of medicine (pulmonary) and co-investigator in the study, who researches the effects of MIF on inflammatory diseases in the lung.

Ibudilast is a type of drug known as a MIF inhibitor. MIF is a gene that regulates the immune response—a driver of inflammation and the so-called "cytokine storm." Over-expression of the gene has been found to play a key role in a number of diseases, including ARDS, asthma, rheumatoid arthritis, lupus, and multiple sclerosis.

Dr. Richard Bucala, chief of rheumatology, allergy, and immunology at Yale School of Medicine and rheumatologist-in-chief at Yale-New Haven Health, is a pioneer in the discovery of drugs that interfere with the MIF pathway to target disease. He was the first to clone MIF and its receptor, and he has developed small-molecule MIF inhibitors to treat autoimmune diseases and cancer. Bucala, who co-directs the Advanced Therapies Group with Dr. Naftali Kaminski, led the partnership with MediciNova. Kaminski is the Boehringer Ingelheim Pharmaceuticals, Inc. professor of medicine (pulmonary).

"We are excited for this partnership opportunity to initiate this study, given the high morbidity and mortality of COVID-19, and the present lack of any evidence-based therapies," said Bucala. "We additionally hope that insights from this trial will help us to better understand how ARDS develops, irrespective of its underlying cause."

COVID-19 patients who are on ventilators for ARDS currently have few treatment options.

"Once a patient is in respiratory failure on a ventilator, there is no specific treatment for reducing lung injury and minimizing ARDS," Chupp said. "All approaches are just to support the patient until the lung heals."

The effort is one of many by Yale's Advanced Therapies Group to find new treatments, diagnostics, and targets for combating COVID-19. Recently, the group [helped to lay the groundwork](#) for [clinical trials](#) of the novel drug sobetirome to treat patients with ARDS, also at Yale-New Haven Hospital.

Provided by Yale University

Citation: Clinical trial for drug to treat severe COVID-19 patients (2020, April 24) retrieved 12 February 2024 from <https://medicalxpress.com/news/2020-04-clinical-trial-drug-severe-covid-.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.