

# Observational study identifies drug that improves survival in sickest COVID-19 patients

August 19 2020

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Researchers at Hackensack Meridian Health, New Jersey's largest and most comprehensive health network, have utilized its statewide observational database of more than 5,000 hospitalized COVID-19 patients to show that a drug normally used in rheumatoid arthritis and cancer treatments, tocilizumab, improves hospital survival in critically-ill patients admitted to the intensive care unit (ICU).

The findings were published in *The Lancet Rheumatology* on Aug. 14, and Hackensack Meridian Health researchers have updated the U.S. Food and Drug Administration and other national leaders of the findings to potentially accelerate improved outcomes.

"Our clinicians and researchers at Hackensack Meridian Health have moved quickly and intelligently since the start of this global health crisis," said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian Health. "Their work in treating this terrible virus, and learning more about it each day, continues to benefit thousands of patients as the pandemic continues."

The study included 630 patients who were admitted to the ICUs of 13 Hackensack Meridian Health hospitals from March 1 to April 22—the height of the pandemic in New Jersey. Among other treatments, tocilizumab was considered for off-label usage for the patients whose respiratory symptoms were declining; many of whom were requiring

mechanical ventilator support. In the observational study 210 patients received tocilizumab, and the other 420 did not.

COVID-19 has three phases: the early or viral phase (with fast viral replication), the pulmonary phase (marked by inflammation and pneumonia as the body tries to fight the virus in the lungs) and the inflammatory phase (in which excessive inflammation reaches and affects many organs and patients are often in the ICU). As part of both the pulmonary and inflammatory phases the [immune system](#) is "supercharged" and secretes in the blood numerous cytokines, particularly interleukin (IL)-6, which induces further inflammation. Tocilizumab is a monoclonal antibody, which binds and blocks the interleukin (IL)-6 receptor and helps dampen the inflammatory response. The activity of tocilizumab was first shown in chimeric antigen receptor (CAR) T-cell therapy, where a similar phenomenon of overactive and growing T cells induce a "cytokine storm." This provided a rationale to try tocilizumab in COVID-19 patients.

The findings showed a statistically-[significant decrease](#) in hospital-related deaths among the patients who received the tocilizumab: a roughly 36 percent decrease in hospital-related mortality among the ICU patients who received the drug, as compared with patients in the ICU who didn't receive it. The data from the outcomes was adjusted to account for multiple factors, including comorbidities, and was assessed using statistical survival models.

Importantly, it appeared that higher levels of a blood test marker of inflammation, C-reactive protein, could predict which ICU patients might benefit most from the tocilizumab therapy, potentially allowing doctors to tailor therapy to those most in need.

"These real-time findings have helped to point us the way forward," said Ihor Sawczuk, M.D., FACS, Hackensack Meridian Health regional

president, Northern Market and chief research officer. "Our clinicians and scientists were at the forefront of COVID research from the beginning of the pandemic."

The results are based on evidence collected in the HMH Universal Observational Database for COVID-19, or RE-COV-RY, which compiles outcomes from 13 Hackensack Meridian Health hospitals throughout New Jersey, using electronic health records (EHRs).

The outcomes division of the John Theurer Cancer Center (JTCC) at Hackensack University Medical Center, under the leadership of Dr. Stuart Goldberg and Dr. Andrew Ip, created a database to guide the analysis of more than 3,000 patients admitted to Hackensack Meridian Health facilities for urgent care. The database has been used to constantly assess COVID-19 treatments over the last several months, including the most promising and high-profile drugs and interventions.

"We need to know more as soon as possible," said Stuart Goldberg, M.D., hematologist/oncologist and chief of the Division of Outcomes and Value Research at John Theurer Cancer Center at Hackensack University Medical Center in New Jersey. "Our database has allowed us to rapidly expand our knowledge of COVID-19 throughout the Hackensack Meridian Health hospital network. We are moving fast to help guide interventions—and potentially save lives."

The lead co-authors on this study are John Theurer Cancer Center hematologist-oncologists Andrew Ip, M.D., from the Division of Outcomes and Value Research and Noa Biran, M.D., from the Division of Myeloma. Both had experience with tocilizumab as part of the JTCC active CAR-T cell transplant program and recognized the potential of this immune modulating therapy in COVID-19.

"This is a great example of our science having impact far beyond

cancer," said Andre Goy, M.D., M.S., physician-in-chief of Oncology, Hackensack Meridian Health.

**More information:** Noa Biran et al, Tocilizumab among patients with COVID-19 in the intensive care unit: a multicentre observational study, *The Lancet Rheumatology* (2020). [DOI: 10.1016/S2665-9913\(20\)30277-0](#)

Provided by Hackensack Meridian Health

Citation: Observational study identifies drug that improves survival in sickest COVID-19 patients (2020, August 19) retrieved 27 April 2024 from <https://medicalxpress.com/news/2020-08-drug-survival-sickest-covid-patients.html>

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