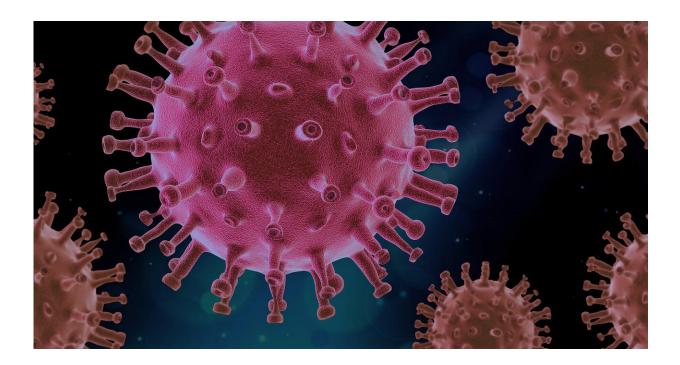


Tricor (fenofibrate) effective in treating severe COVID-19 patients

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The SARS-CoV-2 virus has infected over 165 million people worldwide causing nearly 3.5 million deaths. Recent vaccination efforts have been hindered by multiple coronavirus variants that challenge current vaccines. While infection generally produces a mild disease, in some patients it can develop into a severe inflammatory COVID-19 requiring medical intervention.



Recently, Professor Yaakov Nahmias' team at the Hebrew University of Jerusalem (HU) reported that the new coronavirus causes abnormal accumulation of lipids, which are known to initiate severe inflammation in a process called lipotoxicity. The team identified the lipid-lowering drug TriCor (fenofibrate) as an effective antiviral last year, showing it both reduced lung cell damage and blocked virus replication in the laboratory. These results have since been confirmed by several international research teams. An <u>observational study</u> carried out in multiple clinical centers in Israel was reported last October to support the original findings. The team then launched an interventional clinical study to treat severe COVID-19 patients at Israel's Barzilai Medical Center with support from Abbott Laboratories.

Now, the HU team is reporting promising results of an investigatorinitiated interventional open-label clinical study led by Nahmias and coordinated by Prof. Shlomo Maayan, Head of Infectious Disease Unit at Barzilai. In this single-arm, open-label study, 15 severe-hospitalized COVID-19 patients with pneumonia requiring oxygen support were treated. In addition to standard of care, the patients were given 145 mg/day of TriCor (fenofibrate) for 10 days and continuously monitored for disease progression and outcomes. "The results were astounding," shared Nahmias. "Progressive inflammation markers, that are the hallmark of deteriorative COVID-19, dropped within 48 hours of treatment. Moreover, 14 of the 15 severe patients didn't require oxygen support within a week of treatment, while historical records show that the vast majority severe patients treated with the standard of care require lengthy respiratory support," he added. These results are promising as TriCor (fenofibrate) was approved by the FDA in 1975 for long-term use and has a strong safety record. "There are no silver bullets," stressed Nahmias, "but fenofibrate is far safer than other drugs proposed to date, and its mechanism of action makes is less likely to be variant-specific."

"All patients were discharged within less than a week after the treatment



began and were discharged to complete the 10-day treatment at home, with no drug-related adverse events reported," noted Maayan. "Further, fewer patients reported COVID-19 side effects during their 4-week follow-up appointment," he added. These preliminary findings offer promise to relieve the substantial health burdens experienced by patients who survive the acute phase of COVID-19.

The investigators stressed that while the results were extremely promising, only randomized placebo-controlled studies can serve as basis for clinical decisions. "We entered the second phase of the study and are actively recruiting patients," explained Nahmias, noting that two Phase 3 studies are already being conducted in running South America, the United States (NCT04517396) and Israel (NCT04661930).

The findings were released on *Research Square* and are currently under peer review.

More information: Yaakov Nahmias et al, Metabolic Regulation of SARS-CoV-2 Infection, *Research Square* (2021). <u>DOI:</u> <u>10.21203/rs.3.rs-770724/v1</u>

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