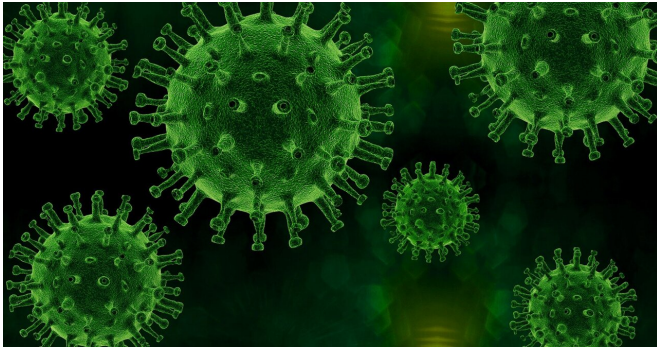


Cholesterol medication fenofibrate fails to cut severe symptoms or death in COVID-19 patients

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After showing promise in early laboratory research, the cholesterol-lowering drug fenofibrate had no significant effect on COVID-19 outcomes in a multicenter international randomized clinical trial led by Penn Medicine scientists. The study results were presented Monday at the American Heart Association's Scientific Sessions 2022 and published in the journal *Nature Metabolism*.

"Despite the promising effects of fenofibrate on SARS-CoV2, the virus that causes COVID-19, our findings convincingly showed that it is not a useful strategy for decreasing [disease severity](#) or preventing bad outcomes in patients with COVID-19," said first author and principal investigator of the trial, Julio Chirinos, MD, Ph.D., a professor of Cardiovascular Medicine and co-director of clinical research for the T32 Training Program in Cardiovascular Biology and Medicine in the Perelman School of Medicine at the University of Pennsylvania.

"Despite the time, complexity, and cost associated with executing rigorous [clinical trials](#), they are essential to evaluating the efficacy of medications

in patients with COVID-19, since the effectiveness of a medication can be substantially different from what in vitro studies may suggest. Clinical trials are necessary before clinical implementation of drug therapies, even for the case of medications that are already widely available for other indications."

Fenofibrate is a widely available, low-cost generic drug previously approved by the United States Food and Drug Administration and many other regulatory agencies to reduce the amount of fatty substances, such as cholesterol and triglycerides, in the blood, while increasing "good" cholesterol (high-density lipoprotein cholesterol known as HDL).

The drug was initially targeted for COVID-19 research as part of an effort to test older, previously approved drugs for potential benefit against the virus. In laboratory studies, it was found that excessive production of certain fat molecules by cells is involved in the [cellular damage](#) caused by SARS-CoV2. Fenofibrate affected the way cells handle fat in a way that reduced viral replication. In additional laboratory studies, fenofibrate also affected the cellular receptor for the virus, reducing viral replication.

To test the drug's effectiveness in people, the study team enrolled 701 participants, with each participant having first experienced COVID-19 symptoms within the past two weeks. The study team randomized assigned 351 patients to be treated with 145 milligrams of fenofibrate (or equivalent preparations in other countries) and 350 with a placebo.

Patients were then ranked based on a novel severity score system that measured disease severity along with factors including death, the use of invasive and non-invasive ventilators, length of

hospital stay, as well as time to hospitalization and symptom severity among outpatients.

Compared with placebo, [fenofibrate](#) had no significant effect either on severity scores or death from any cause, among other metrics. There was similarly no difference in outcomes up to 30 days after the initial randomization. Importantly, the findings were consistent across countries and were not affected by sex, age, race, body mass index, diabetes status, or the time when patients initiated treatment.

The authors noted there could be a number of potential explanations for the drug's failure to achieve the same results in humans that it did in laboratory cells.

"COVID-19 is complex and involves not only its [toxic effect](#) on cells but also on a complex set of systemic host responses," said co-author Jordana B. Cohen, MD, MSCE, an assistant professor of Renal-Electrolyte and Hypertension at Penn.

"Therefore, cellular effects of drugs observed in a petri dish system may fail to translate to beneficial effects in people with COVID-19 as a result of a wide range of potential phenomena in whole organisms. Our trial reinforces the importance of not equating laboratory efficacy with clinical efficacy in the setting of COVID-19."

The study team called for further studies to assess whether other interventions designed to affect cellular metabolic pathways can impact outcomes in people with COVID-19.

More information: Julio Chirinos et al, A randomized clinical trial of lipid metabolism modulation with fenofibrate for acute coronavirus disease 2019, *Nature Metabolism* (2022). [DOI: 10.1038/s42255-022-00698-3](#)

Conference: [professional.heart.org/en/meet ... /scientific-sessions](#)

Provided by Perelman School of Medicine at the University of Pennsylvania

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