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Study Finds Ivermectin 'Did Not Prevent' Severe COVID-19, but Doctors Alliance Calls It 'Misleading'

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A peer-reviewed study in which researchers concluded that ivermectin treatment during early COVID-19 “did not prevent” severe disease in high-risk patients has been criticized by an alliance of doctors for being “misleading.”

In the open-label randomized clinical trial, also referred to as the “The I-TECH Randomized Clinical Trial,” published in the JAMA Internal Medicine journal on Feb. 18, researchers said their findings “do not support the use of ivermectin for patients with COVID-19.”

The study involved results from 490 patients with mild to moderate COVID-19 in Malaysia. Participants were aged 50 and over, with at least one documented comorbidity. People who did not develop symptoms or who had severe COVID-19 were not included in the trial.

The trial was conducted in 20 hospitals and a COVID-19 quarantine center in the country between May 31 and Oct. 25, 2021. Of the group, 249 participants received standard care, while 241 received a course of oral ivermectin over five days in addition to standard care.

Researchers said they found that 21.6 percent of patients in the ivermectin group and 17.3 percent in the standard care group progressed to “severe disease.”

They wrote that there were no statistically significant differences between the two cohorts in how many needed mechanical ventilation, had to be admitted to intensive care unit (ICU), or died within 28 days after having been admitted to the hospital.

Ivermectin is a generic medicine developed in the 1970s and is now widely used against roundworm

parasites to treat river blindness and elephantiasis, as well as to treat scabies, lice, and rosacea in humans. William Campbell and Satoshi Omura in 2015 won the Nobel Prize in Physiology or Medicine for the drug's discovery and applications.

Ivermectin has been praised by some doctors as a life-saving early treatment for COVID-19. At least two groups, the Front Line COVID-19 Critical Care Alliance (FLCCC) and the British Ivermectin Recommendation Development Group (BIRD), have been advocating for the off-label use of ivermectin to treat COVID-19 in its early stages.

The World Health Organization features ivermectin on its List of Essential Medicines. It is also approved as an antiparasitic agent by the U.S. Food and Drug Administration (FDA).

However, the FDA has not approved the drug to treat or prevent COVID-19 in humans. According to the FDA, side effects of ivermectin include skin rash, nausea, and vomiting.

The American Medical Association, the American Pharmacists Association, and the American Society of Health-System Pharmacists, said in a joint

statement in September 2021 they were against its use to treat COVID-19 outside of a clinical trial.

A box of ivermectin (French packaging), an anti-parasitic drug and also a potential treatment for COVID-19, in Clamart, France, on April, 2, 2021. (Shutterstock)

Criticism

On Feb. 19, the FLCCC rejected the conclusions of the I-TECH Randomized Clinical Trial and called it “misleading” and “underpowered.” The group also said that the study authors reached “a conclusion that inexplicably departs from the study’s own data.”

Dr. Paul Marik, a neurocritical care doctor who is the chairman and chief scientific officer of the FLCCC, said the study was “clearly designed to fail.”

“The authors selected out patients with mild or moderate disease who were at low risk of having a major event. Consequently it was grossly underpowered for any meaningful patient-centered outcome,” he said in a statement, later adding, “It is clear that a massive study would have been far better to determine greater statistical significance.”

Dr. Pierre Kory, FLCCC president and chief medical officer, said the study’s conclusion is “flat out wrong and highly misleading.”

“In the study’s control group, two-and-a-half times more patients had to be placed on mechanical ventilation—and there were three times more deaths in the control group,” Kory, a pulmonologist, said in a statement. “This shows that ivermectin causes a 75 [percent] risk reduction in death and further strengthens metadata of ivermectin’s large mortality benefits in severe COVID.”

Kory was referring to the results of the study, which found that four people in the ivermectin group

needed mechanical ventilation compared to 10 people in the control group; six people in the ivermectin group needed admission to ICU compared to eight in the control group; and three people in the ivermectin group died, compared to 10 people in the control group.

Meanwhile, FLCCC co-founder Dr. Keith Berkowitz noted that the strongest p-value in the entire study, which is the measure of statistical significance, was for the 28-day hospital mortality, which was at .09. A p-value of less than .05 would be considered statistically significant.

Berkowitz commented that the study was “too limited and small to even be randomized,” but despite that, the results still “trended in favor of ivermectin.”

The FLCCC also criticized the fact that all the study participants had been experiencing symptoms for five days when they were enrolled in the study, and said that ivermectin treatment started too late in the disease.

“As those of you who have been following the FLCCC know, early treatment (within the first ONE

OR TWO DAYS of symptom onset) is critical to slow virus replication and impeded progression to severe disease," the FLCCC said. "So the authors of the study reported that ivermectin was not helpful in preventing progression to severe disease—among study patients who had been started too late in their disease at the start. Nevertheless, the authors concluded that [ivermectin] was not helpful in the treatment of COVID."

"This study is in line with the major medical journals which will only publish negative studies on ivermectin and hydroxychloroquine," Marik said. "They simply will not publish any of the dozens of positive studies that have emerged. This constitutes enormous, deliberate publication bias, which is immensely injurious to scientific truth—and to patients throughout the world."

The FLCCC group accused the I-TECH Randomized Clinical Trial and JAMA of having "[dismissed] the totality of peer-reviewed, published evidence (and a number of summary meta-analyses) showing repeatedly shorter times to clinical recovery, fewer hospitalizations, and far less

death when COVID patients are treated with ivermectin.”

The Epoch Times has reached out to JAMA and the study’s corresponding author, Dr. Steven Chee Loon Lim, for comment.