Single-dose treatment reduces COVID-19 hospitalization risk by half for high-risk patients in phase 3 trial

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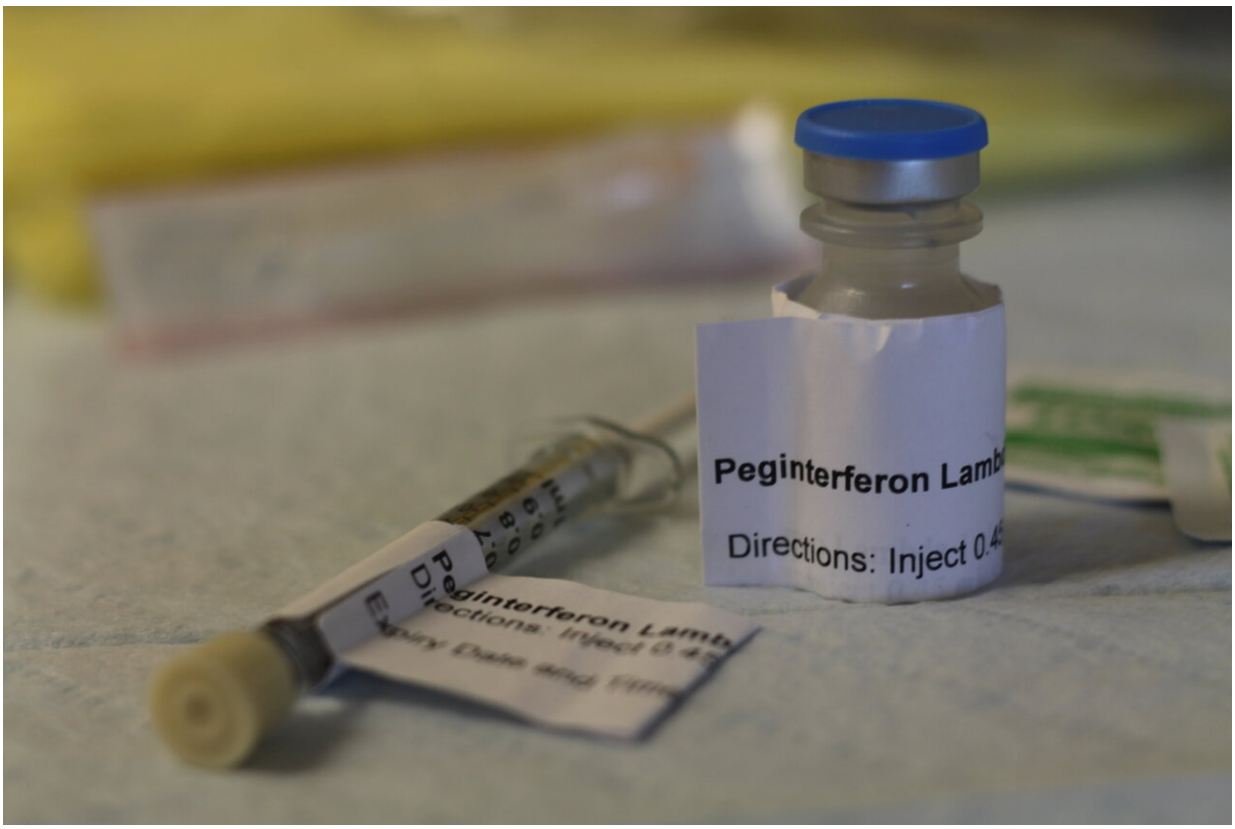

Credit: University Health Network

A single-dose of the antiviral drug peginterferon lambda reduced by half the risk of hospitalization or a visit to the Emergency Department due to

COVID-19, according to a study published today in the *New England Journal of Medicine*.

The multi-center phase 3 TOGETHER clinical trial—designed to test a new therapy in a real setting—evaluated the use of this drug in more than 1,900 outpatients at high risk of developing complications from COVID-19.

Patients who received a single-dose subcutaneous injection of peginterferon lambda within seven days of their first COVID-19 symptom had a 50 percent lower risk of needing to be admitted to hospital when compared to people who received a placebo.

The trial was one of the first to test treatment in a largely vaccinated population. The research team found that a similar effect was seen in those who had received the vaccine—84 percent—as in those who were unvaccinated. The team also saw the benefits of treatment across multiple COVID-19 variants, including the highly transmissible omicron variant.

This study follows a previous phase 2 trial performed at UHN that showed that peginterferon lambda accelerated clearance of the virus.

"This much larger trial shows us that the antiviral benefits we previously observed translate to clinical benefit. The results conclusively show that this is an effective therapy to treat COVID-19 to reduce the risk of complications," says Dr. Jordan Feld, one of the lead authors of the study, Interim Director of the Toronto Center for Liver Disease and Co-Director of the Schwartz Reisman Liver Research Center and the R. Phelan Chair in Translational Liver Research at UHN.

"An important feature of this treatment is that it is not affected by changes or mutations in the virus, because it works by stimulating the

body's own response to viral infection," added Dr. Feld, who is also a Senior Scientist at the Toronto General Hospital Research Institute at UHN and a professor in the Department of Medicine at the University of Toronto.

Study participants reported few or no side effects, with no significant differences seen between the group that received the actual treatment and the group that received a matching placebo.

"This could be an important addition to our arsenal to fight COVID-19, especially for high-risk patients who may not be able to use currently available treatments because of side effects or drug interactions with medications they take," says Dr. Feld.

All participants were either aged 50 or older or had a health condition that put them at higher risk for severe COVID-19, such as diabetes, hypertension, obesity, being a transplant recipient, cancer patient, among other conditions. The effect of the treatment was even more pronounced in people who received the drug within three days of symptom onset, consistent with other antiviral medications for COVID-19.

The study was done in partnership with the Pontifical Catholic University of Minas Gerais, Brazil, where first author Dr. Gilmar Reis and his team recruited the majority of participants and helped analyze the data. The study was also done in collaboration with Dr. Edward Mills, at McMaster University, and Professor Jeffrey Glenn at Stanford University.

The TOGETHER Study is a phase 3 trial that was based on the phase 2 study led by Dr. Feld in Toronto last year.

More information: Early Treatment with Pegylated Interferon Lambda for Covid-19, *New England Journal of Medicine* (2023). DOI:

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