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Added anti-viral improves response, halves duration of hepatitis C treatment

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The addition of the anti-viral drug telaprevir to a standard treatment for hepatitis C can shorten the duration of therapy and increase the number of patients who can be cured of their disease, according to the results of study coordinated by investigators from the Duke Clinical Research Institute (DCRI).

"Standard treatment for the most common type of hepatitis C is 48 weeks of a combination of two drugs, peginterferon alfa-2a and ribavirin, which cures less than half of patients and has significant side effects that make it very difficult for some patients to continue their treatment," said John McHutchison, M.D., a hepatologist and gastroenterologist and researcher at the DCRI, and lead investigator on this study. "Our study found that by combining the standard therapy with the direct anti-viral drug telaprevir, we could reduce the duration of treatment by 50 percent, to 24 weeks, and, at the same time, improve the cure rate by 50 percent."

The researchers published their findings in the April 30, 2009 issue of the *New England Journal of Medicine*. The study was funded by Vertex Pharmaceuticals, the maker of the drug telaprevir, a protease inhibitor that works by blocking an enzyme that the hepatitis C virus needs in order to replicate itself.

In a randomized, Phase IIb, double-blinded, 37-center study of telaprevir in combination with peginterferon alfa-2a and ribavirin, the researchers examined the responses of 250 patients on four trial arms.

The researchers measured rates of sustained viral response - or SVR - defined as 24 weeks during which the hepatitis C virus remains undetectable in the body after the completion of therapy.

"We observed that 67 percent of patients who received standard therapy for 48 weeks in conjunction with 12 weeks of telaprevir were cured of their hepatitis C," McHutchison said. "The rate was 61 percent in the group that took the standard therapy for only 24 weeks in combination with 12 weeks of telaprevir, suggesting that many patients may respond to treatment in only six months as compared to about eleven months, which is significant for this patient population, because the side effects of treatment can be so intense."

The group that received standard therapy for up to 48 weeks had a sustained viral response rate of 41 percent, McHutchison said.

The most frequently reported adverse side effect associated with telaprevir was a rash that was manageable in some patients, but caused others to discontinue the treatment, McHutchison said.

"Treating genotype 1 hepatitis C, the most common form of the infection in the United States, can be challenging because the side effects are difficult for many people to endure, the duration of treatment is long, and traditionally less than half of patients are able to be cured of their disease," said Andrew Muir, M.D., a gastroenterologist at Duke and a senior investigator on the study. "Even though telaprevir does produce side effects of its own, its addition to standard therapy was able to improve response rates and shorten the duration of treatment necessary - either one alone would have been an advance, and to be able to achieve both is a significant step in the right direction when it comes to treating hepatitis C."

Peginterferon alfa-2a is an antiviral drug given by injection that is also

used to treat HIV and hepatitis B; it works in conjunction with a drug called ribavirin, a nucleoside analogue, to suppress the viral activity of hepatitis C. Side effects can include severe flu-like symptoms, depression, fatigue, insomnia and anemia.

Worldwide, an estimated 180 million people have a chronic hepatitis C virus infection, and hepatitis C is a leading cause of cirrhosis and liver cancer. It is also the most common condition leading to liver transplantation in the United States.

Source: Duke University Medical Center (news : web)