

Hepatitis C treatment reduces the virus but serious liver problems may progress

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Patients with chronic hepatitis C and advanced liver disease who did not respond to previous standard therapy experienced significant decreases in their liver enzymes, viral levels, and liver inflammation following treatment with long-term pegylated interferon. However, the treatment did not slow or prevent the progression of serious liver disease.

These findings come from the clinical trial, Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) and were reported at the annual meeting of the American Association for the Study of Liver Disease in Boston on November 5, 2007. HALT-C is funded by the National Institutes of Health (NIH) with additional support from Hoffmann-La Roche Inc.

"The HALT-C trial unequivocally demonstrated that maintenance therapy with peginterferon does not prevent progression of liver disease among patients who have failed prior treatments," said James Everhart, M.D., project scientist for HALT-C and a program director for the Division of Digestive Diseases and Nutrition, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the principal sponsor of HALT-C at NIH. "These results add to the incentive to develop more effective drugs that will benefit patients with severe liver disease due to hepatitis C."

HALT-C, a randomized multicenter trial of 1,050 patients with chronic hepatitis C who had failed prior treatment to eradicate the infection, assessed whether long-term treatment with peginterferon alfa-2a reduced

the development of cirrhosis, liver failure, or liver cancer. The 517 patients randomized to the treatment arm received 90 micrograms of peginterferon in weekly injections for 3.5 years. The 533 patients in the control arm underwent the same follow-up and care as the treated patients including liver biopsies, quarterly clinic visits, and blood tests. All patients had advanced liver fibrosis, a gradual scarring of the liver that puts patients at risk for progressive liver disease.

The outcomes assessed in HALT-C were death, liver cancer, ascites (excess fluid in the abdomen), or encephalopathy (brain and nervous system damage), and for those who did not have cirrhosis initially, the development of cirrhosis. At the end of the study, 34.1 percent of the patients in the treated group and 33.8 percent of the patients in the control group had experienced at least one outcome. Patients in the treated group had significantly lower blood levels of the hepatitis C virus and less liver inflammation. However, there was no major difference in rates of any of the primary outcomes between groups.

Among treated patients, 17 percent stopped peginterferon by one year and six months and 30 percent stopped the drug two years later. Adverse events such as infections, musculoskeletal or digestive problems were the most common reasons patients stopped taking the drug.

Viral hepatitis C infects more than 100 million persons worldwide and as many as 4 million persons in the United States. Hepatitis C ranks with alcohol abuse as the most common cause of chronic liver disease and leads to about 1,000 liver transplants in the United States each year. The best current antiviral therapy consists of pegylated interferon given by injection in combination with oral ribavirin prescribed for about 6 months to a year. This therapy eliminates the virus in about 50 percent of infected patients.

Source: NIH/National Institute of Diabetes and Digestive and Kidney

Diseases

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