

Drug Boosts Platelets in Hepatitis C Patients

It's not a cure, but this may be some of the best news patients infected with the hepatitis C virus (HCV) have heard in a long time: A new drug, eltrombopag, appears to be effective in boosting low platelet counts, one of the major reasons why patients can't endure antiviral treatments.

Other drugs that can restore normal platelet functions are infusions or injections; eltrombopag is a pill taken just once a day.

Researchers at Duke University Medical Center and other centers world-wide studied eltrombopag (marketed as Promacta in the U.S. and Revolade in Europe by GlaxoSmithKline) in 74 patients with low platelet counts and cirrhosis of the liver due to HCV infection. They found that it boosted platelet counts in a majority of patients at each of three dosage levels, enabling most of them to continue or start conventional antiviral treatment.

The findings appear in the current issue of the *New England Journal of Medicine*.

"We feel this is an important development for many people infected with the hepatitis C virus world-wide," says Dr. John McHutchison, professor of medicine and associate director of the Duke Clinical Research Institute. "A significant number of patients with HCV infection will at some point develop platelet problems that will compromise their getting the best treatments we have. Anything we can do to prevent that from happening would improve their care."

It's estimated that 4 million people in the U.S. and 170 million world-wide carry the hepatitis C virus. The virus causes inflammation and scarring in the liver, and while it is curable in about half of those who have it, it can lead to significant liver damage, liver cancer and death in others. HCV infection is a common cause of cirrhosis and the most common reason for a liver transplant.

Platelets are cells made in the bone marrow that are important in clot formation, and serious bleeding can occur if platelet levels fall too low. Some diseases, like HCV infection, can cripple the body's ability to manufacture platelets, but so can some medical treatments. Cancer patients, for example, can experience plummeting platelet levels when undergoing chemotherapy.

In the phase II, multi-center trial, participants were randomized to a control group or to receive 30, 50, or 75 milligrams of eltrombopag daily. The patients had platelet levels ranging from 20,000 to 70,000 (145,000 to 450,000 is normal).

A phase II trial is designed to test the safety and efficacy of a drug at different doses, and the Duke study found that eltrombopag worked in a dose-dependent manner, meaning that patients got a better response with increasing amounts of the drug. Seventy-four percent of those in the trial who took the lowest dose saw their platelet counts go up significantly, while 79 percent and 95 percent of the participants saw increases with the higher doses.

Eltrombopag does cause side effects. Some of the patients complained of headaches, dry mouth, abdominal pain and nausea.

"We are encouraged by these results and are already working on another multi-center, international, phase III trial where we hope these results will be confirmed," says McHutchison.

The study was sponsored by GlaxoSmithKline, which manufactures eltrombopag. McHutchison and many of the coauthors also report having received grants, consulting, advisory or speaking fees from the company.

Source: Duke University Medical Center

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