MedicalXpress

Studies of experimental hepatitis C drug show promise for preventing recurrence in liver transplant

October 31 2013

New drug therapies offer promise to some hepatitis C sufferers whose transplanted livers are threated by a recurrence of the disease, including some patients who have had no treatment options.

The encouraging findings are contained in two new studies by a collaboration of researchers across the U.S. – as well as in Spain and New Zealand – including Dilip Moonka, M.D., medical director of Liver Transplant at Henry Ford Hospital.

Both studies are being presented at the annual meeting of the American Association for the Study of Liver Disease being held in Washington, DC, Nov. 1-5.

Both studies focused on the experimental anti-viral drug sofosbuvir, a direct-acting oral medication that may take the place of injectable interferon, which causes severe side effects in some patients.

The U.S. Food and Drug Administration is expected to decide in early December whether to approve its use for treating hepatitis C. Last week, the Antiviral Drugs Advisory Committee of the FDA voted unanimously in support of approval for sofosbuvir-based therapies for the treatment of chronic hepatitis C.

Chronic hepatitis C, which afflicts an estimated 3 million people in the

U.S. alone, is a blood-borne viral disease that leads to scarring and deterioration of the liver. It is particularly insidious because patients usually don't develop symptoms until the scarring – or cirrhosis – is well underway.

Sofosbuvir, which belongs to a class of drugs known as nucleotide analogue polymerase inhibitors, acts at the molecular level by interfering with the RNA of the hepatitis C virus.

In the first newly released study, researchers tested it as an alternative to interferon, a naturally occurring protein that plays a role in fighting viral infections, but commonly produces a range of serious side effects.

The researchers used it in combination with ribavirin, which also inhibits the hepatitis C virus by interfering with its RNA to stem the replication of the virus and slow the progression of the disease. They sought to test the drug combination's effectiveness in preventing recurrence of hepatitis C in liver transplant recipients.

A total of 61 chronic hepatitis C patients with liver cancer were enrolled in the study and given both sofosbuvir and ribavirin daily for up to 48 weeks before liver transplant. All of the patients had well-compensated cirrhosis, meaning their bodies were still functioning without too much trouble despite liver scarring.

The researchers found that the new drug combination was both safe and effective in such patients and prevented post-transplant recurrence of the hepatitis C virus in more than 60 percent of them.

In the second newly released study, researchers focused on liver transplant recipients whose severe hepatitis C recurred after surgery and who either couldn't tolerate or didn't respond to approved antiviral therapies – leaving them with no other effective treatment options.

In such cases, experimental drugs can sometimes be tested under "compassionate use" protocols.

The researchers reported that as of April, 115 patients were approved for compassionate use of sofosbuvir combined with ribavirin and/or the anti-viral drug peginterferon. At the time of their report, 63 had started treatment.

After several weeks of treatment and study, the researchers concluded that patients with severe recurrence of hepatitis C after receiving transplanted livers were able to tolerate the drug regimen, which produced strong anti-viral effects.

Provided by Henry Ford Health System