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The Portland area is one of the sites for an AmFAR clinical study of combination drug therapy for hepatitis C and HIV

by Bob Roehr

The American Foundation for AIDS Research has begun recruitment for the first clinical trial of combination therapy for hepatitis C among those who are also HIV-positive. The 18-month study will involve 200 patients at 20 sites around the nation, including Portland.

Protease combination therapy has dramatically beaten back HIV for many, but that success has allowed time for more slowly developing medical conditions, such as hepatitis C, to emerge.

This second viral infection attacks the liver, scarring it and reducing liver function over the course of decades. Liver damage can make it harder to metabolize certain drugs, including protease inhibitors. It can ultimately lead to complete liver failure and death.

Some people living with HIV/AIDS who carry hepatitis C may not even know they have it. Until recently there was little effective therapy, so many doctors didn't even bother to screen for the hepatitis C virus. Furthermore, the standard screening test misses as many as half of the hepatitis C cases among those with HIV.

Many people with hepatitis C were infected through tainted blood products utilized prior to a screening program initiated in 1990.

Today, new infections are likely to come through sharing needles, cocaine straws, and blood during rough sex. Condoms offer protection, and the risk via oral sex is believed to be very small.

Interferon alpha is currently the only federal Food and Drug Administration-approved therapy for hepatitis C. It brings sustained viral repression in only 20 percent of those who complete the regimen.

A combination adding the synthetic nucleoside ribavirin seems to suppress the virus in about 50 percent of cases. The combination has been submitted to the FDA for market approval.

So far, none of the trials of interferon and ribavirin have dealt with HIV-positive people. But anecdotal evidence suggests disease progression and reaction to treatment will be similar whether one is infected only with hepatitis C virus or coinfected with HIV.

AmFAR brought physicians participating in the clinical trial to a day-long briefing in New York City on April 1.

The 18-month study involves 48 weeks of double-blind, placebo-controlled treatment in which half the subjects will receive interferon and ribavirin, and the other half will receive interferon and a placebo, explained Kevin Frost, director of clinical research for AmFAR.

The trial will measure hepatitis C viral load at several points during the regimen, as well as six months after it is completed, to see if there is sustained viral suppression.

Volunteers must have any HIV drug regimen stabilized at least four weeks prior to beginning this trial. Part of the initial screening process is a liver biopsy—a potentially painful procedure—to determine what, if any, liver scarring is present.

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Participants will be taught to inject interferon under their skin, much as a diabetic does with insulin. Injections will be administered at least three times a week, or perhaps daily, for the duration of the trial.

Side effects of interferon range from very mild to severe flulike symptoms and are often dose-related. Ribavirin is a pill with generally mild side effects. Both can cause anemia and loss of blood platelets.

■ *For further information about the trial, contact Norma Martinez of the Portland-based Research & Education Group at 229-8428.*