SOUTHWESTERN NEWS

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UT SOUTHWESTERN RECRUITING PATIENTS FOR NATIONAL HEPATITIS C STUDY

DALLAS – June 14, 2000 – Doctors at UT Southwestern Medical Center at Dallas are recruiting individuals with hepatitis C who have not responded to previous treatments for a new study that will test the effectiveness of maintenance drug treatments in slowing the disease's progression to cirrhosis of the liver.

The National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health awarded UT Southwestern a $1.68 million grant to conduct the Hepatitis C Anti-Viral Long-Term Treatment Against Cirrhosis (HALT C) study. Nine institutions across the country will be recruiting a total of 1,200 patients, with UT Southwestern enrolling 135 patients.

More than 4 million Americans are infected with hepatitis C, a viral infection of the liver contracted through blood-to-blood contact. Over time it can cause fibrosis of the liver, or scarring, which may progress to cirrhosis.

"The problem with hepatitis C is that it's a very slow, low-grade, asymptomatic kind of infection," said Dr. William Lee, professor of internal medicine and lead investigator of the study at UT Southwestern. "Most people don't know they have this disease until they're diagnosed during a physical examination or attempt to donate blood."

Being diagnosed with hepatitis C is not a death sentence because there are treatments that can eradicate the hepatitis virus. There are some individuals who will never develop cirrhosis or need to be treated.

Lee, who is chairing the protocol committee of the national study, said minorities and women will be encouraged to participate; they have been under-represented in previous hepatitis C trials.

During the lead-in phase of the study all patients will receive the best treatment currently available.

"Patients will have a weekly shot of long-acting interferon plus ribavirin," said Lee.

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"Even if they've failed previous treatment attempts, there is still a possibility that they can be cured using this new treatment."

Individuals who don't respond to this treatment combination will be randomized into one of two groups: One will continue to receive interferon treatment, and the other will not. Both will receive follow-up evaluation for three and a half years.

"Liver biopsies and ultrasound exams will be done in both groups to monitor disease progression during the study," Lee said. "Although many patients will want to be in the treatment arm of the study, this involves continuation of interferon treatment for more than a four year period with its attendant side effects."

A person who has experienced extreme side effects from treatment, cannot tolerate having liver biopsies, or doesn't want to be randomized into the treatment or nontreatment groups may not want to enroll in this study, Lee said.

To be considered for the study, candidates must have fibrosis or cirrhosis confirmed by liver biopsy and have documentation that previous interferon treatment has failed.

For more information or to enroll in the study, call Kim Yarbrough at 214-648-3690.

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