



Suppressive Long-term Antiviral Management Of Hepatitis C Virus (HCV) And Hiv-1 Co-Infected Participants

Purpose of this study

To determine whether long-term treatment with pegylated-interferon alfa-2a (PEG-IFN) slows the rate of liver damage caused by hepatitis C virus (HCV) in people infected with both HCV and HIV for whom other treatment failed to clear the HCV. People who have been previously treated for HCV and those who have never been treated will be allowed to enter the study. All subjects must have had a liver biopsy obtained within the last 104 weeks (about 2 years) prior to entering the study.

Step 1: Subjects who have never been treated for HCV or who have previously taken at least 12 weeks of any interferon (IFN)-based therapy (e.g. IFN, IFN + ribavirin, PEG-IFN, or PEG-IFN + ribavirin) but did not clear the HCV, can be entered into Step 1, Arm A. These subjects cannot have received any HCV treatment in the past 4 weeks. Subjects in Step 1 will receive PEG-IFN as an injection under the skin weekly and 2-3 tablets of ribavirin twice per day for 12-18 weeks.

For subjects who will enter Step 2, a liver biopsy will be done at the completion of Step 1.

Step 2: Some subjects will enroll in Step 2 after completing Step 1 and other subjects will skip Step 1. The subjects who enroll directly into Step 2 must currently be taking PEG-IFN + ribavirin, must have completed 12-18 weeks of this treatment, and must have tolerated the medications. Step 2 is for subjects who have not adequately cleared the HCV by week 12 of PEG-IFN + ribavirin therapy.

Subjects in Step 2 will be assigned either to receive PEG-IFN as an injection under the skin weekly for 72 weeks or to receive no HCV treatment and just be monitored for 72 weeks.

Step 3: Subjects who tolerate Step 1 treatment and have adequately cleared the HCV by the end of Step 1 will enter Step 3. Subjects will continue the Step 1 treatment until they have been on the treatment for a total of 72 weeks during the study. This includes receiving PEG-IFN weekly and 2-3 tablets of ribavirin twice per day. Subjects will be monitored for an additional 24 weeks after completion of their treatment.

All subjects will have a liver biopsy done at the end of the study. Participation will last either 72 weeks (about 1 ½ years) or 96 weeks (about 2 years).

Study entry requirements

- HIV positive and Hepatitis C positive men or women greater than 18 years of age.
- Currently on stable antiretroviral therapy for at least 8 weeks prior to entry and no plans to change therapy for at least 12 weeks after entry OR on no antiretroviral therapy prior to entry and no plans to start therapy for 24 weeks after entry.
- CD4 >200 cells/mm³ and HIV-1 RNA <50,000 copies/ml – 42 days prior to entry.
- No evidence of decompensating liver disease
- No substance abuse
- No acute illness

You will be provided with a consent form to review before deciding to participate. If you agree to participate, other procedures will be performed to evaluate your eligibility.

Principal Investigator

Ardis Moe, MD

For more information, please call 310.557-1891

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Expiration Date: