ACTG A5294
(Participant Summary Sheet)
A Prospective, Phase III, Open-Label Study of Boceprevir, Pegylated0Interferon Alfa 2b and Ribavirin in HCV/HIV Coinfected Subjects (BIRTH)

A Multicenter Trial of the Aids Clinical Trials Group (ACTG)

Brief Description

You are being asked to take part in this research study because you are infected with both HIV (the virus that causes AIDS) and HCV (a virus that causes hepatitis; an inflammation of the liver, specifically genotype 1 which is one of the main types of hepatitis C). This is often referred to as coinfection. People participating in this study can be either treatment naïve (individuals who have never taken HCV medications) or treatment experienced (individuals who have previously taken HCV medications). Treatment for the HCV virus usually consists of a combination of two drugs known as pegylated-interferon alfa 2b (PEG-IFN) and ribavirin (RBV). Treatment response in HCV infected persons is measured by SVR (sustained virologic response, which is the proportion of patients who have no measurable virus in blood six months after completing treatment). SVR is lower among persons who have HIV coinfection compared to those who have HCV infection alone and is higher among those who have never been treated before compared to those who have previously failed treatment. Among treatment naïve HIV and HCV genotype 1 coinfected individuals treated with PEG-IFN and RBV, SVR is generally less than 25% (vs. 40-45% in those with HCV alone); among previously treated persons, SVR is achieved in 10% or less. In 2011, two new drugs were approved in the U.S. (Boceprevir [BOC] and Telaprevir) to treat HCV in those infected with HCV alone. These agents, when used in combination with PEG-IFN/RBV have yielded SVR rates of 65-72% in subjects with HCV infection alone. However, studies of these agents in those coinfected with HIV are lacking.

Purpose of this Study

This study is being done to see if adding a third drug to this combination is safe and whether it will help people with both HIV and HCV better fight their HCV. The third drug that this study is investigating has already been approved by the Food and Drug Administration (FDA) recently for the treatment of people who are infected with HCV alone.

Requirements to Enter Study

Group A (Step 1):

Never received treatment for HCV with standard interferon, PEG-IFN, or experimental agents used to treat HCV, with or without RBV.

Group A (Step 2):

Completion of step 1 and no demonstration of HCV virologic/treatment failure.

Group B:

Received any treatment with standard interferon or PEG-IFN with or without RBV at any time provided the last dose of such treatment was ≥ 90 days prior to study entry.

Groups A and B:

-Documented HIV infection and ≥ 18 years of age
-Presence of chronic HCV infection with a positive HCV RNA > 180 days ago and current HCV viremia or a positive liver biopsy demonstrating chronic hepatitis