

Study of the Consequences of the Protease Inhibitor Era (SCOPE)

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Project Description: The Study of the Consequences of the Protease Inhibitor Era (SCOPE) is a prospective cohort study dedicated to evaluating the long-term consequences of highly active antiretroviral therapy among HIV-infected persons. Eligible participants must have a baseline CD4+ T-cell count > 50 cells/mm³ and a nadir CD4+ T-cell count < 500 cells/mm³. Treatment history must meet one of the following categories: (1) untreated (target n=100): no antiretroviral therapy for the preceding 24 weeks; (2) virologic responders (target n=100): stable combination therapy with a plasma HIV RNA < 50 copies/ml during the preceding 24 weeks and (3) virologic non-responders (target n=200): stable combination therapy with a plasma HIV RNA > 500 copies/ml during the preceding 24 weeks. Participants are seen every four months, where a detailed questionnaire is administered regarding antiretroviral use and adherence as well as transmission risk behavior. Plasma, serum, peripheral blood mononuclear cells, and saliva are obtained at each study visit.

Significance: The relationship between viral replication, CD4 T cell depletion and disease progression has been well described among untreated HIV-infected adults. However, the relationship between these factors has not been adequately described in the era of highly active therapy, especially in patients who fail to maintain durable suppression of viral replication. We have therefore established a prospective cohort study with two primary objectives: (1) to observe the long-term outcome of patients failing to achieve complete viral suppression with combination therapy and (2) to develop a repository of clinical, epidemiologic, and behavioral data as well as biologic specimens aimed at supporting investigation of the factors associated with virologic, immunologic and clinical progression among treated patients.

Interesting Findings: Enrollment in the initial phase of the project is complete: 506 patients have been enrolled (427 male, 70 female, 9 male-to-female transgender). The mean age is 45.2 years, and there is a diverse racial distribution (56% White; 25% African-American; 9% Latino; and 10% other). Of the 506 patients, 136 are treatment naïve or untreated, 114 are virologic responders and 256 are virologic non-responders.