

## ACTG A5241: The OPTIONS study

**Title of Study:** The Optimized Treatment that Includes or Omits NRTIs (OPTIONS) Trial: A Randomized Strategy Study for HIV-1 Infected Treatment-Experienced Subjects Using the cPSS to Select an Effective Regimen.

**Brief Description:** This study will look at whether newer anti-HIV drugs are safe and effective in a group of HIV-infected persons whose current HIV medicines are not working. The study will also test whether using a specific type of medicines called nucleoside reverse transcriptase inhibitors (NRTIs) are needed to treat HIV in persons failing their current medicines. Finally this study will test whether a medicine resistance test score called the cPSS is able to predict which drugs will work best in people whose virus is resistant to specific HIV medications.

### Requirements to Enter Study:

- HIV-1 infected people at least 16 years of age
- HIV viral load (HIV level) currently 1000 copies/mL or higher
- Currently on an HIV drug regimen that includes a protease inhibitor (PI)
- Have resistance to multiple types of HIV medications
- Had exposure to multiple types of HIV medications

**Treatment: Step One (up to 75 days):** You will remain on your current anti-HIV regimen. You will have blood drawn and a group of study physicians will review your resistance testing, your cPSS score and the type of virus that you have, as well as your previous medication history. The study physicians will recommend one or more study drug combinations that will give a cPSS test score above 2 to you and your primary doctor. Some of the possible combinations include different types of pills; other combinations include pills and a medicine called enfuvirtide which must be injected. If there are two or more combinations that may work for you, your primary doctor and you will pick one. If the study physicians and your primary doctor can not choose a study drug combination that will give a cPSS score above 2, you might enter part two of the study if there are still enough spaces left in this group. Otherwise, if there is only one combination that may work, you will be expected to take that combination.

The study physicians will also recommend a combination of NRTIs based on the results of the resistance test. Again, if there is more than one possible NRTIs combination choice, your primary doctor and you will be able to pick one you might take. Once you and your study physician choose the study drug combination and the NRTI combination you want to start, you will be randomized (chosen as if by a flip of a coin). The randomization will determine whether or not you will take the NRTIs that you selected along with the other study medicines.

**Step Two (96 weeks):** In part two of the study, you will receive your medicines and return to the clinic at least 8 times for a blood draw and health check up. During this time, you will have testing of your HIV viral load (HIV level) and CD4 cell counts, and will have tests to make sure the new drugs are safe. If the new drugs do not work to make your viral load low enough, you will have another resistance test done as part of the study; results of these tests will be given to your primary doctor.

**Study Drugs** The anti-HIV drugs that will be provided through the study are: enfuvirtide, raltegravir, darunavir, tipranavir, etravirine and maraviroc. Which of these drugs are recommended for you depends on the results of the testing done in the Part One of the study. Although they may be recommended by the study doctors, NRTIs and ritonavir will not be provided through the study; you will have to get these on your own.

**Duration of Study:** The study will last approximately 26 months (a little over 2 years).

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