

ACTG A5247 Participant Summary Sheet

Title: A Phase II, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of ZOSTAVAX[®] (Zoster Vaccine Live) in Human Immunodeficiency Virus (HIV)-1-Infected Adults on Potent Combination ART with Conserved Immune Function.

Short Title: Response to Zoster vaccine in HIV-1-infected adults.

Description: Herpes Zoster is a reactivation of the varicella-zoster virus. This virus is the virus that causes chickenpox. After the initial infection with chickenpox the virus stays dormant in the nerve system of the body. Reactivation can cause a painful blister-like rash on the skin (Herpes Zoster, also known as Shingles). Frequently the discomfort from the rash can last for several months after the blisters have healed. ZOSTAVAX[®] (Zoster Vaccine Live) has been shown to decrease the incidence and severity of Herpes Zoster in older adults without HIV infection. There is a 3 out of 4 chance of receiving the active vaccine and 1 out of 4 chance of receiving the placebo (inactive solution).

Purpose: This study will determine how well the ZOSTAVAX[®] (Zoster Vaccine Live) is tolerated by HIV-1-infected adults with healthy immune systems who are on antiretroviral therapy and also to determine how effective the vaccine is in the development of protection against reactivation of the varicella virus.

Requirements: You must be 18 years of age or older, be on antiretroviral therapy, and have a CD4 count ≥ 200 (24 subjects in the CD4+ 200-349 cells/ μ L stratum and 24 subjects in the CD4+ ≥ 350 cells/ μ L stratum.) for Stage I or ≥ 200 for Stage II. You can not have previously received a vaccine for chickenpox or herpes zoster.

Treatment: You will receive a vaccine or placebo injection at study entry and at week 6.

Length: You will be on study for up to 12-24 weeks with telephone contact at week 24.

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