

Basics of RV144

Trial: A Phase III randomized, double-blinded, placebo-controlled trial of Sanofi Pasteur live recombinant ALVAC-HIV (vCP1521) priming with VaxGen gp120 B/E (AIDSVAX B/E) boosting in HIV-negative Thai adults

Experimental Vaccine: PRIME: canarypox viral vector with *env* and *gag-pol* (ALVAC-HIV (vCP1521)) / BOOST: *env* protein/gp120 subunits (AIDSVAX B/E)

Study Question: Whether the prime-boost vaccine combination was safe and effective at reducing rates of HIV infection or reducing viral load in vaccine recipients who became HIV infected over the course of the study. Trial participants' primary risk factor for HIV was sexual exposure.

Sponsor: US Army Surgeon General

Funders: Division of AIDS, National Institute of Allergy and Infectious Diseases, NIH; US Army Medical Research and Materiel Command

Collaborators: US Military HIV Research Program (MHRP)/Walter Reed Army Institute of Research, the Thai Ministry of Public

Health, Mahidol University, the Armed Forces Research Institute of Medical Sciences—US and Thai components, the National Institute of Allergy and Infectious Diseases, Sanofi Pasteur, Global Solutions for Infectious Diseases and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.

Participants: 16,402 HIV-negative Thai men and women between the ages of 18 and 30

Location: Forty-seven health centers and eight clinical sites in Rayong and Chonburi provinces, Thailand

Results: Initial data showed that vaccine recipients were approximately 31 percent less likely than placebo recipients to become infected with HIV. However, the data suggest that the effect of the vaccine could have ranged from a 1.1 percent reduction in HIV acquisition to a 51.2 percent reduction in HIV acquisition for trial participants who received the active vaccine compared to those who received the placebo. It is important to consider the full statistical analyses to gain a more complete understanding of the results. (See box on next page for a more detailed analysis of the results.) There was no observed effect on viral load. Additional analysis is ongoing.