

SAFTY AND IMMUNOGENECITY OF AN HIV SUBTYPE B AND E PRIME - BOOST VACCINE COMBINATION IN HIV - NEGATIVE THAI ADULTS.

Sorachai Nitayaphan¹, Punnee Pitisuttithum³, Chitraporn Karnasuta², Chirapa Eamsila¹, Mark de Souza², Patricia Morgan², Victoria Polonis^{2,a}, Michael Benenson², Tom VanCott⁵, Silvia Ratto-Kim^{2,a}, Jerome Kim^{5,a}, Darawan Thapinta⁴, Robin Garner⁵, Valai Bussaratid³, Pricha Singharaj², Raphaelle el Habib⁶, Sanjay Gurunathan⁶, William Heyward⁷, Deborah Birx⁵, John McNeil^{5,a}, and Arthur E. Brown², for the Thai AIDS Vaccine Evaluation Group^b.

1. Royal Thai and 2. US Army Components, Armed Forces Research Institute of Medical Sciences, and 3. Vaccine Trial Faculty of Tropical Medicine, Mahidol University, Bangkok, and 4. Faculty of Nursing, Chiang Mai University, Chiang Mai, Thailand; 5. Walter Reed Army Institute of Research, Rockville, Maryland; 6. Aventis Pasteur, Swiftwater, Pennsylvania; 7. VaxGen, Brisbane, California.

ABSTRACT

ALVAC-HIV (vCP1521) and AIDSVAX B/E were evaluated in a phase 1/2 trial of human immunodeficiency virus (HIV)-negative Thai adults. Of 133 volunteers enrolled, 122 completed the trial. There were no serious vaccine-related adverse events, nor were there intercurrent HIV infections. Lymphoproliferative responses to glycoprotein 120 E were induced in 63% of the volunteers, and HIV-specific CD8 cytotoxic T lymphocyte responses were induced in 24%. Antibody responses increased in frequency and magnitude in association with the dose level of AIDSVAX B/E. Binding and neutralizing antibodies to the MN strain were induced in 100% and 98%, respectively, of the volunteers receiving 600 microg of AIDSVAX B/E, and such antibodies to E strains were induced in 96% and 71%, respectively, of these volunteers. This vaccine combination was well tolerated and was immunogenic, meeting milestones for advancement to phase 3 evaluation.

(JID 2004:190 (15 August) * BRIEF REPORT.)