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

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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.

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