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OA04-06 LB. Post-infection cellular immune responses in recipients following ALVAC-HIV® + AIDSVAX® B/E prime-boost vaccination in the Thai Phase III Trial

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Background

The phase III prime-boost trial of ALVAC-HIV® (vCP1521) and AIDSVAX® B/E spanned 2003 to 2009 in Thailand. Both candidates express HIV CRF 01_AE and subtype B antigens, the predominant circulating HIV-1 subtypes in Thailand. This preliminary study assessed cell-mediated immune (CMI) responses, viral load and CD4 counts in a subset (N=47) of anti-retroviral naïve incident infections (< 270 days after estimated infection) that occurred during the trial.

Methods

Study participants were randomized 1:1, vaccine:placebo. The immunization regimen was 0, 1, 3 and 6 months for ALVAC-HIV®, with AIDSVAX® being administered at 3 and 6 months. Cytotoxic T lymphocyte (CTL) assays were conducted on freshly isolated peripheral blood mononuclear cells (PBMC) in a standard chromium release assay using autologous EBV-transformed B cells as targets (N=47). Interferon-gamma (IFN-γ) ELISpot assays were performed using cryopreserved PBMC (N=43). Target antigens for both CMI assays matched those of the vaccine candidates. Concurrent viral load and CD4 counts were measured using commercial assays. HIV genotyping was performed using the multiregion hybridization assay.

Results

Data are still blinded with respect to immunization status. The median time from infection to CMI assessment was 164 days (range: 113-265). The frequency of HIV-specific CD8+ CTL activity was 64%, with equivalent responses to Env (19/47) and Gag/Pol (18/47) antigens. HIV-specific IFN-γ ELISpot responses were measured in 47% of subjects, but the response was predominantly to Gag – 37% versus 19% for Env. Median viral load and CD4 counts were 25338 copies/ml (range: <50-272509) and 571 cells/μl (range: 220-1067), respectively. CRF01_AE was the predominant infecting subtype (82%; 37/45).

Conclusion

Robust CD8+ mediated CTL responses to HIV antigens expressed by the ALVAC-HIV® immunogen were observed in participants who became infected during the trial. Determining the relevance of these responses to viral control and/or CD4 T cell counts following un-blinding (October, 2009) constitutes a high priority.