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rAd5 prime/NYVAC-B boost regimen is superior to NYVAC-B prime/rAd5 boost regimen for both response rates and magnitude of CD4 and CD8 T-cell responses

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Background

HVTN 078 is a randomized, double blind phase 1b clinical trial to evaluate the safety and immunogenicity of heterologous prime/boost vaccine regimens (NYVAC-B/rAd5 vs. rAd5/NYVAC-B) in healthy, HIV-1 uninfected, Ad5 seronegative adult participants.

Methods

The rAd5 vaccine expressed clade B Gag-Pol and the gp140 of HIV-1 92RW020 (clade A), HxB2/Bal-V3/ΔV1V2 (clade B) and 97ZA012 (clade C). The NYVAC-B vaccine expressed clade B Gag-Pol-Nef and the gp120 of Bx08 (clade B). 80 healthy, HIV-1 uninfected, Ad5 seronegative volunteers, aged 18 to 45 years, were randomized to the placebo arm (n=5) or one of 4 treatment (T) arms: T1 (n=30), 2xNYVAC-B/1xrAd5 (10E10); T2 (n=15), 1xrAd5 (10E8)/2xNYVAC-B; T3 (n=15), 1xrAd5 (10E9)/2xNYVAC-B; T4 (n=15), 1xrAd5 (10E10)/2xNYVAC-B.

Intracellular cytokine staining responses (percent of CD4+ and CD8+ T cells producing IFN-γ and/or IL-2 in response to stimulation with global PTE peptides) were assessed two weeks after the final vaccination.

Results

For CD4+ T cells, the overall response rates for IFN-γ and/or IL-2 among the vaccinees were 42.9%, 93.3%, 92.3%, and 85.7% for T1-T4, respectively; and the median response magnitudes for positive responders were 0.26%, 0.76%, 0.40%, and 0.76% for T1- T4, respectively. Both response rates ($p<0.01$) and magnitudes ($p<0.03$) of CD4+ T-cell responses were significantly lower in T1 compared to the other three treatment groups. For CD8+ T cells, the overall response rates were 65.5%, 73.3%, 76.9% and 85.7% for T1-T4, respectively; and median response magnitudes for positive responders were 0.32%, 0.99%, 1.86%, and 1.65%, respectively. Response rates were not significantly different between groups; however, response magnitudes were significantly lower in T1 compared to the other three arms ($p<0.04$).

Conclusion

Priming with rAd5 followed by NYVAC-B boost is superior to priming with NYVAC-B followed by rAd5 boost for both response rates and the magnitude of CD4+ and CD8+ T-cell responses.

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