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Phase 2a safety and immunogenicity testing of DNA and recombinant modified vaccinia ankara virus vaccines expressing virus-like particles

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Background

The Phase 2a HVTN 205 trial was undertaken to further compare full-dose regimens of DNA priming with MVA boosting and MVA priming and boosting.

Methods

150 vaccinia-naïve participants were inoculated i.m. via needle and syringe with 3 mg of pGA2/JS7 DNA at months 0 and 2, and 1x108 TCID50 of MVA/HIV62B at months 4 and 6 (DDMM regimen). 75 participants received 1x108 TCID50 of MVA/HIV62B at months 0, 2, and 6 (MMM regimen) and 75 received placebo. While the safety data are still blinded, the vaccine regimens appeared safe and well tolerated. Immune studies were performed at 2 weeks following the final vaccination.

Results

Similar to Phase 1 testing, the DDMM regimen induced higher rates of T cell responses whereas the MMM regimen induced higher rates of antibody responses. CD4 T cell responses were elicited in 65% of the DDMM and 43% of the MMM recipients (p=0.01) whereas CD8 T cells were induced in 22% and 16%, respectively. The majority of T cells were directed against Gag with fewer against Env and only occasional responses to Pol. gp120 IgG antibodies were demonstrated in 45% and 68% of the DDMM and MMM recipients, respectively (p=0.001). gp41 IgG antibodies were seen in over 90% of both groups. The magnitudes of serum IgG responses exceeded the magnitudes of serum IgA responses by >10 fold with higher IgG to IgA responses being present in the MMM group (p=0.03). The antibody avidity index to the gp41 immunodominant epitope, a preclinical correlate of protection against infection demonstrated levels of affinity maturation comparable to preclinical studies. Sporadic weak neutralizing activity against Tier 1 and Tier 2 viruses was seen in both groups and was greater for MVA alone.

Conclusion

The vaccine safety data and immune responses seen here are supportive of further testing.

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