Background

These two trials under Africa-Europe collaborations aim at addressing two factors relevant for Africa i.e helminth infections and HIV-1 diversity. EV06 used a novel combination of DNA expressing clade C Env, Gag and Pol-nef co-administered with AIDSVAX®/B/E Env protein to study the effect of S. mansonii on vaccine responses. GREAT is a recently awarded trial using a 2nd generation improved conserved tHIVConsvX T-cell vaccine candidate combined with bivalent mosaic design to increase breadth and protective epitopes.

Methods

EV06 enrolled 72 males and females aged 18–45, half infected with S. mansoni (SM+). In each arm 30 received vaccine and 6 placebo at week 0, 4 and 24. Responses were evaluated at week 0, 6, 26 and 36. Humoral responses were measured as binding IgG against a panel of HIV-1 envelope glycoproteins and as neutralizing antibodies (Nabs), using TZMbl cells and tier 1 pseudoviruses. Cellular responses were measured as HIV-specific CD4+ and CD8+ T-cell by IFN-γ ELISpot and multi-cytokine intracellular staining flow cytometry. GREAT will be a phase IIa trial and preparation for efficacy trials in Kenya, Uganda and Zambia testing ChAdOx1.tHIVconsv5 and ChAdOx1.tHIVconsv6 followed by MVA.tHIVconsv3 and MVA.tHIVconsv4 on week 2 (Arm 1) or week 8 (Arm 2).

Progress

Differences in binding IgG response rates were observed in vaccinated participants against the vaccine matched clade C V1V2 (gp70–96ZM651.02 V1V2) at week 6: 56% among SM+ versus 86% among SM (p=0.039). At week 36, response magnitudes were statistically lower in the SM+ against gp120 and gp140 proteins (p=0.04 for both). SM+ also had lower Nabs and ELISpot responses at various time points. Still blinded data on the first 20 volunteers show 80% responders for CD4 T cell at w26 and 70% CD8 responders at w36. These trials will provide more data on challenges facing HIV vaccine development in Africa.

OA-033 THE RESULTS OF THE EV06 DNA-PROTEIN COMBINATION TRIAL AND PLANS FOR GREAT, AN ECDFP2-FUNDED CONSERVED-MOSAIC EPIOTPE HIV VACCINE TRIAL

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