

Poster presentation

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## PI4-03. HIV-specific T-lymphocyte proliferative responses induced by a multigene multiclade HIV-1 DNA/MVA heterologous vaccine in Tanzanian volunteers

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### Background

A phase I/II HIV vaccine trial (HIVIS 03) employing a multiclade, multigene HIV-1 DNA prime/MVA boost vaccine among healthy volunteers is ongoing in Dar es Salaam, Tanzania.

### Methods

Sixty healthy HIV negative volunteers including 15 females, were randomised to 3 groups and were injected at months 0, 1 and 3 with plasmid DNA vaccine (produced by KI/SMI and Vecura, Sweden) containing gp160 of HIV-1 subtypes A, B, C; rev B; p17/p24 gag A, B and Rtmut B, at 1 mg i.d. (n = 20) or 3.8 mg i.m. (n = 20) or placebo (n = 20) using the Biojector. At month 9, a single i.m. injection with MVA 10<sup>8</sup> pfu of MVA/CMDR expressing HIV-1 genes *env*, *gag*, *pol* of CRF01A\_E (produced by NIAID and WRAIR, USA) or placebo was administered. T-lymphocyte proliferative (TLP) responses to AT-2 inactivated HIV-1 antigen from virus isolates/clade MN/B, KNH1144/A, TZA125/C and CM235/A\_E were tested by a standard <sup>3</sup>H-thymidine uptake assay. TLP was reported as stimulation index (SI) and SI above 6 was considered positive based on mean reactivity at baseline in 40 volunteers.

### Results

Two weeks after the 3rd DNA/placebo injection, 24 of 52 (46%) volunteers had positive TLP responses. Two weeks and two months after the HIV-MVA/placebo boost, 35 of 48 (73%) and 32 of 44 (73%) volunteers had positive TLP responses, respectively. Thus far, 33 volunteers have been tested six months after the HIV-MVA/placebo boost and 20 (61%) have positive TLP responses. There was a high degree of cross reactivity as shown by strong proliferative responses to all four isolates tested. The TLP responses were sustained and 6 months after the HIV-MVA boost the greatest reactivity was seen against CM235/A\_E. The study remains blinded.

### Conclusion

HIVIS03 DNA-MVA vaccine has so far demonstrated strong HIV-specific T-lymphocyte proliferative responses with a high degree of cross clade reactivity.