Immunization with the HIV/AIDS vaccine candidate MVA-B is safe in HIV-1 negative healthy volunteers: Results of the RISVAC02 clinical trial.

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Title: Immunization with the HIV/AIDS vaccine candidate MVA-B is safe in HIV-1 negative healthy volunteers: Results of the RISVAC02 clinical trial.

Background: We present, without unblinding the study, the overall safety results of a phase I, doubled blind placebo-controlled trial of an attenuated HIV poxvirus vector.

Methods: The trial was conducted at 2 Spanish Centers in 30 non-HIV-infected volunteers. Inclusions criteria were: 1) age 18-55, 2) low risk of HIV-1 infection, and 3) absence of smallpox specific antibodies and no history of previous smallpox vaccination. After entering the study, volunteers were randomly allocated to receive 3 intramuscular (i.m) injections of MVA-B (n=24) or placebo (n=6). The primary end-point were grade 3-4 adverse events (AE), reported here, and immunogenicity. The vaccine used was a modified poxvirus strain MVA expressing HIV-1 Bx08gp120 and IIIB gagpolnef from clade B (referred as MVA-B) administered i.m at 1 x 108 pfu per dose. Immunizations were performed at 0, 4 and 16 weeks. All volunteers were followed until week 52.

Results: For this trial 24 men and 6 women were entered. Median age was 27 years (IQR 22-32). All but one reported 174 AE during follow-up (5,8 events/volunteer); 168 were grade 1-2, and 6 grade 3-4. Fifty two of grade 1-2 AE were considered as definitely related to vaccination, and most of them were injection site reactions. There were 5 AE grade 3, but none was considered related to vaccination. Finally, one AE was graded as 4, and it was considered as definitely related to vaccination. In this case, one volunteer showed a positive HIV-1 ELISA test but with a negative Western Blot on week 4. On week 16 and 52 HIV-1 ELISA and Western Blot test were both negative.

Conclusions: MVA-B vaccine is safe and well tolerated. Most AE are grade 1-2 and related to the injection site. Pending on the immunogenicity analysis, these data supports further exploration of MVA-B as HIV vaccine candidate.