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Commentary

Advances in HIV Vaccine Clinical Trials

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DESCRIPTION

Long-term safety is critical for the development and later use of a vaccine to prevent HIV/AIDS. Likewise, the persistence of vaccine-induced antibodies and their impact on HIV testing must be established. IAVI has sponsored several Phase I and IIA HIV vaccine trials enrolling healthy, HIV-seronegative African volunteers. Plasmid DNA and viral vector based vaccines were tested. No vaccine-related serious adverse events were reported. After completion of vaccine trials conducted between 2001–2007, both vaccine and placebo recipients were offered enrolment into an observational long-term follow-up study (LTFU) to monitor potential late health effects and persistence of immune responses. At scheduled 6-monthly clinic visits, a health questionnaire was administered; clinical events were recorded and graded for severity. Blood was drawn for HIV testing and cellular immune assays. 287 volunteers were enrolled; total follow-up after last vaccination was 1463 person years (median: 5.2 years). Ninety-three 93% of volunteers reported good health at their last LTFU visit. Infectious diseases and injuries accounted for almost 50% of the 175 reported clinical events, of which over 95% were mild or moderate in severity. There were 30 six pregnancies, six incident HIV infections and 14 volunteers reported cases of social harm. Persistence of immune responses was rare. No safety signal was identified. No potentially vaccine-related medical condition, no immune mediated disease, or malignancy was reported. HIV vaccines studied in these trials had a low potential of induction of persisting HIV antibodies.

The long-term follow up (LTFU) study was a prospective, observational study to monitor both vaccine and placebo recipients from previous HIV vaccine trials for any late health effects and the persistence of vaccine-induced immune responses. Placebo recipients were followed up as successfully as vaccine recipients. No significant or potentially vaccine-related medical problems have been detected. No autoimmune or potentially immune mediated disease and no malignancy have been reported in enrolled volunteers. These observations are consistent with previously published data on long-term safety of HIV candidate vaccines.

To our knowledge, our paper is the only one reporting on long-term safety of HIV vaccines in healthy African adults.

The most common clinical events reported were mild or moderate infectious diseases, and the proportion of volunteers with respective symptoms or conditions did not differ between vaccine and placebo recipients. This observation is consistent with data published on background morbidity, as assessed by unsolicited adverse events in clinical trial participants.

Three of the IAVI sponsored trials testing an MVA-based HIV vaccine began prior to, and one within a few weeks after the publication that, rarely, pericarditis/myocarditis may occur a few weeks after vaccination against smallpox. No such event occurred in our HIV vaccine trials, at the peak time observed for recipients of the replication-competent DryVax®. Therefore we did not look for late occurrences following our highly attenuated MVA. Surveillance in subsequent IAVI trials and a meta-analysis have shown no such events following MVA to date.

No background data on congenital anomalies are available from the countries where the LTFU study was conducted. The types of anomalies observed are also known to occur in children born to women in industrialized countries and to women who have not participated in HIV vaccine trials. The numbers are too small to draw any conclusion on a teratogenic potential of the vaccines tested.

The summary analysis of clinical events reported during long-term follow-up is unremarkable. No safety signal has been identified. These data contribute to the long-term safety profile of HIV vaccines tested in healthy, HIV-seronegative African adults. For HIV vaccines studied to date, there was only a small potential for VISR, but current and future vaccines may induce stronger antibody responses that potentially pose difficulties for the individual volunteers, as they may be falsely identified as infected with HIV.

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