

Study examines safety, immune response of candidate Ebola vaccines

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In a study appearing in the April 19, 2016 issue of *JAMA*, Matthew D. Snape, F.R.C.P.C.H., M.D., of the University of Oxford, United Kingdom, and colleagues conducted a phase 1 trial to evaluate the tolerability and immunogenicity of two candidate Ebola vaccines, an adenovirus type 26 vector vaccine (Ad26.ZEBOV), and a modified Ankara vector vaccine (MVA-BN-Filo).

The recent outbreak of Ebola virus disease in West Africa has caused in excess of 28,600 cases and 11,300 deaths since the first cases were identified in December 2013 in Guinea. The international response has included the accelerated clinical development of several candidate Ebola vaccines. In nonhuman primates, an Ad26-vectored <u>vaccine</u> was able to generate up to 75 percent protection from Ebola challenge.

For this study, participants (healthy volunteers, 18-50 years old) were randomly assigned to 4 groups, within which they were simultaneously randomized 5:1 to receive study vaccines or placebo. Those receiving active vaccines were primed with Ad26.ZEBOV or MVA-BN-Filo and boosted with the alternative vaccine 28 or 56 days later. A fifth, openlabel group received Ad26.ZEBOV boosted by MVA-BN-Filo 14 days later. The trial was conducted in Oxford, U.K.

Among 87 study participants, 72 were randomly assigned to 4 groups of 18, and 15 were included in the open-label group. Four participants did not receive a booster dose; 67 of 75 study vaccine recipients were followed up at 8 months. An immune response was observed after



primary immunization with Ad26.ZEBOV; boosting by MVA-BN-Filo resulted in sustained elevation of specific immunity. Immunization with Ad26.ZEBOV or MVA-BN-Filo did not result in any vaccine-related serious adverse events.

"Our data showed that, in contrast to MVA-BN-Filo, Ad26.ZEBOV priming generated an initial immune response, and there is evidence for protection from this vaccine given alone in nonhuman primate models. Therefore, this priming dose would be expected to generate at least partial protection against Ebola; for this reason, Ad26.ZEBOV prime schedules with MVA-BN-Filo boost are currently being further evaluated in phase 1, 2, and 3 studies," the authors write.

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