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Title: Safety and Immunogenicity of a two dose Ebola vaccine among pregnant women in Rwanda

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Risk of death for both mother and fetus following Ebola virus infection is extremely high. In this study, healthy women in Rwanda aged ≥ 18 years were randomized to two-dose Ebola vaccination (Ad26.ZEBOV, MVA-BN-Filo) during pregnancy (group A) or postpartum (group B). Unvaccinated pregnant group B women served as control. This was a parallel, randomized, controlled, open-label, single-center trial to evaluate the safety (primary endpoint-outcomes of interest and serious adverse events (SAEs)) and immunogenicity (secondary endpoint) of the two-dose Ebola vaccination. Among 3,484 women screened, 2,013 were randomized, and 2,012 women and 1,945 infants born alive were descriptively analyzed. Adverse outcomes of interest occurred in women (5.2% in group A and 7.3% in group B) and infants (26.0% in group A and 25.6% in group B). The most common maternal outcome of interest was pathways to preterm birth (3.2% in group A and 3.4% in group B), and the most common infant outcome of interest was small for gestational age (14.3% in group A and 11.8% in group B). Maternal/fetal and neonatal/infant SAE frequencies were comparable between groups (9.8% in group A, 9.0% in group B and 21.9% in group A, 15.9% in group B, respectively). Anti-Ebola virus glycoprotein-specific binding antibody response (secondary endpoint) was sustained in $\geq 90\%$ of women at 1 year postdose 1. In group A, binding antibodies were detected in cord blood (99%) and infant serum (95%) samples 14 weeks postbirth. The trial met all primary and secondary objectives. Ad26.ZEBOV, MVA-BN-Filo did not raise concerns regarding adverse maternal/fetal or neonatal/infant outcomes, had no unexpected safety issues, and induced binding antibody responses in women and offspring through passive transfer.

