

Single-dose, live oral cholera vaccine CVD 103-HgR (Vaxchora) protects against *Vibrio cholerae* challenge and induces serum vibriocidal antibodies (SVA) in adults

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Background: The attenuated recombinant *Vibrio cholerae* O1 strain CVD 103-HgR (Vaxchora®) is a single-dose oral vaccine indicated for active immunization against cholera.

Methods: Vaxchora vaccine was evaluated in three phase 3 studies in adults. In the human challenge study, healthy adults between 18-45 years were randomized 1:1 to receive either a single dose of vaccine or placebo. Subsets of participants were challenged with 10⁵ colonies of a wild-type El Tor Inaba strain at 10 and 90 days after vaccination, and the primary endpoint was prevention of moderate/severe diarrhea. A randomized, double-blind, placebo-controlled study to demonstrate lot consistency enrolled participants aged 18–45 years. Subjects randomly received a single dose from one of three lots; immunogenicity and safety were assessed. Immunogenicity and safety in older adults were evaluated in a randomized, double-blind placebo study of subjects aged 46–64 years.

Results: In the challenge study, vaccine protective efficacy against moderate/severe diarrhea was 90.3% (day 11) and 79.5% (day 91). Vaccine-induced increases in vibriocidal antibody titer strongly correlated with protection. In the lot consistency study, GMTs at 10 days post-vaccination were equivalent across all lots tested, and the rate of seroconversion 10 days post-vaccination was 93.5% in Vaxchora vaccine recipients. The seroconversion rate in older adults was 90.4% and non-inferior to the rate in the 18-45-year-olds. Overall reactogenicity profiles were similar across the three studies. No serious adverse events were related to vaccine.

Conclusion: A single-dose of Vaxchora vaccine may be used for prevention of cholera in adult travelers visiting high-risk areas.