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Abstract

Objectives

To investigate safety, efficacy, and immunogenicity of live quadrivalent rotavirus vaccine (QRV) containing human-bovine (WC3) reassortant rotavirus serotypes G1, G2, G3, and P1a.

Study design

This was a randomized, double-blinded, placebo-controlled trial. During 1993 to 1994, at 10 US study sites, 439 healthy infants $\hat{\wedge}^{1/2}$ to 6 months of age, were enrolled to receive 3 doses of oral QRV or placebo at approximately 8-week intervals.

Results

The vaccine was generally well tolerated; no serious vaccine-related adverse experiences were reported. Risk differences and 95% confidence intervals suggested no differences between vaccine and placebo recipients in the incidences of fever, irritability, vomiting, or diarrhea during the 14 days after any dose. QRV was 74.6% efficacious (95% CI: 49.5%, 88.3%) in preventing rotavirus acute gastroenteritis (AGE), regardless of severity and 100% efficacious (95% CI: 43.5%, 100%) in preventing severe rotavirus AGE through one rotavirus season. Serotype G1 was identified in most infants with rotavirus AGE. A 3-fold rise in serum neutralizing antibody to G1 was observed in 57% (45/79) of vaccinees. A 3-fold rise in serum anti-rotavirus IgA and fecal anti-rotavirus IgA was observed in 88% (162/185) and 65% (104/159) of vaccinees, respectively.

Conclusions

QRV was generally well tolerated, immunogenic, and highly effective against rotavirus gastroenteritis.



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Abbreviations

ACIP, Advisory Committee on Immunization Practices; AGE, Rotavirus acute gastroenteritis; QRV, Quadrivalent rotavirus vaccine; RRV-TV, Tetravalent rhesus-based reassortant rotavirus vaccine; SNA, Serum neutralizing antibody

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