Efficacy, Immunogenicity and Safety of a Human Rotavirus Vaccine RIX4414 in Singaporean Infants

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Abstract

Introduction: This was the first study conducted to evaluate the efficacy of 2 oral doses of the human rotavirus vaccine, RIX4414 in Singaporean infants during the first 3 years of life. Materials and Methods: Healthy infants, 11 to 17 weeks of age were enrolled in this randomised (1:1), double-blinded, placebo-controlled study to receive 2 oral doses of RIX4414 vaccine/placebo following a 0-, 1-month schedule. Vaccine efficacy against severe rotavirus (RV) gastroenteritis (Vesikari score \( \geq 11 \)) caused by wild-type RV strains from a period starting from 2 weeks post-Dose 2 until 2 and 3 years of age was calculated with 95% confidence interval (CI). Immunogenicity and safety of the vaccine were also assessed. Results: Of 6542 infants enrolled, 6466 were included in the efficacy analysis and a subset of 100 infants was included in the immunogenicity analysis. Fewer severe RV gastroenteritis episodes were reported in the RIX4414 group when compared to placebo at both 2 and 3 year follow-up periods. Vaccine efficacy against severe RV gastroenteritis at the respective time points were 93.8% (95% CI, 59.9 to 99.9) and 95.2% (95% CI, 70.5 to 99.9). One to 2 months post-Dose 2 of RIX4414, 97.5% (95% CI, 86.8 to 99.9) of infants seroconverted for anti-RV IgA antibodies. The number of serious adverse events recorded from Dose 1 until 3 years of age was similar in both groups. Conclusion: Two oral doses of RIX4414 vaccine was immunogenic and provided high level of protection against severe RV gastroenteritis in Singaporean children, during the first 3 years of life when the disease burden is highest.

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