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A Dose-Escalation Safety and Immunogenicity Study of Live Attenuated Oral Rotavirus Vaccine 116E in Infants: A Randomized, Double-Blind, Placebo-Controlled Trial.

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BACKGROUND: Rotavirus infections cause approximately 122,000 deaths among Indian children annually.
METHODS: The neonatal rotavirus candidate vaccine 116E was tested in a double-blind, placebo-controlled dose-escalation trial in India. Two doses of the Vero cell-adapted vaccine were evaluated. One hundred eighty-seven infants received a vaccine dose of [Formula: see text] focus-forming units (ffu) and 182 received a dose of [Formula: see text] ffu in a 1:1 randomization with placebo recipients. Infants received the vaccine at 8, 12, and 16 weeks, separately from routine vaccines.
RESULTS: No significant differences in clinical adverse events or laboratory toxicity were observed between vaccine and placebo recipients. There were no vaccine-related serious adverse events. A 4-fold increase in rotavirus immunoglobulin A titer was observed in 66.7% and 64.5% of infants after the first administration and in 62.1% and 89.7% of infants after 3 administrations of doses of [Formula: see text] ffu and [Formula: see text] ffu, respectively; the differences between these groups and placebo recipients were statistically significant.
CONCLUSIONS: Three administrations of vaccine doses of [Formula: see text] ffu and [Formula: see text] ffu were safe. The [Formula: see text]-ffu dose of 116E demonstrated a robust immune response after 3 administrations. These favorable results warrant further development of the vaccine candidate and provide optimism that vaccinating infants in the developing world will prevent serious sequelae of rotavirus infection. Clinical trials registration. NCT00439660 and ISRCTN57452882.

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