

Bharat Biotech announces Rotavirus vaccine

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The Indian Rotavirus Vaccine Development Project (RVDP), announced encouraging results from a recent Phase I clinical trial of two live, natural reassortant, candidate rotavirus vaccines, 116E and I321, conducted in New Delhi, India.

The development project includes, the Department of Biotechnology, Bharat Biotech International, Hyderabad, India, Society for Advanced Studies, New Delhi, India, Centres for Disease Control, Atlanta, GA, National Institutes of Health, the Indian Institute of Science, Bangalore, India and Stanford University, Palo Alto, CA. For the past several years, the RVDP have worked together.

In this randomised, double blind trial, 90 healthy infants aged eight to twelve weeks were assigned into three groups. They received a single oral dose of either one of the two candidate rotavirus vaccines, strains 116E or I321, or placebo. Participants were monitored for adverse events, and their stool and blood specimens were obtained to assess vaccine take, measured by vaccine virus shedding and a rotavirus antibody response. The trial demonstrated that both vaccines were well tolerated and safe.

Following the encouraging results of this phase I trial, the RVDP is planning clinical trials with cGMP vaccine lots, produced by Bharat Biotech. They plan to use the same strains, 116E and I321. Bharat Biotech has successfully developed the 116E and I321 human rotavirus strains as vaccine candidates. These trials are planned to begin in Q2 of 2006.