Significant differences in the cumulative 5-year vaccine protection among different age groups or vaccine administration were not detected. Vaccine protection was clearly evident in the third to fifth year of follow-up in persons vaccinated at ages five years and older and during the second year in children vaccinated at 1-4 years of age. There were no statistically significant differences in the occurrence of reported adverse events between recipients of vaccine and placebo. The most common adverse events reported were diarrhea, fever, vomiting and abdominal pain. This study conducted in subjects aged one year or older (no upper age limit) along with the other non-pivotal studies formed the basis for the licensure and WHO pre-qualification of Shanchol.4,5

Shanchol also confers herd protection as demonstrated in the above study using geographic information system (GIS) analysis. In the GIS output, herd protection was assessed by evaluating association between vaccine coverage among the population residing within 250 m of the household and the occurrence of cholera in that population. Using this approach, the risk of cholera among placebo recipients was demonstrated to be inversely related to neighborhood-level vaccine coverage, and the trend was highly statistically significant (P<0.01).4

A double-blind placebo controlled safety and immunogenicity study was conducted in Dhaka, Bangladesh. A total of 530 subjects -110 adults and 220 children (more than 1 year of age), were administered 2 doses of Shanchol or placebo at an interval of two weeks. Overall, the seroconversion (> 4 fold rise in serum vibriocidal antibodies) against V. cholerae O1 Inaba, Dharjeeling India, O139, O1 Ogawa and O1 Inaba was observed in 72.53% (60 adults and 78.13% children), 74.53% (64 adults and 76.72% children) and 46.22% (28 adults and 59.98% children) vaccine recipients respectively as compared to 5.7% (7 adults and 4.5% in children), 6.76% (5 adults and 7.5% in children) and 7.28% (6 adults and 8.13% in children) in the placebo groups respectively. No significant differences were observed in safety events between the vaccine and placebo recipients.

Immune responses after one and two doses of Shanchol oral cholera vaccine measured in a double-blind, randomized, placebo-controlled trial at ages 18-40 years and 17-17 years residing in Kolkata, India. Overall 61% & 91% of adults and 89% and 97% of children and 86% and 92% of children exhibited > 4 fold rise in serum O1/Vibrio cholerae O1 Ogawa antibody titre from baseline dose 1 and 2 respectively. Responses to V. cholerae O139 were less pronounced but followed a similar pattern. This study demonstrated that in a cholera-endemic area, the vaccine elicited the expected immune responses after a single dose of oral vaccine.

An open label post-hoc trial aimed to evaluate the safety and immunogenicity of Shanchol was conducted in Yemen, a cholera-endemic area in India. A total of 280 volunteers - 100 adults and 180 children (more than 1 year of age) were administered at least two doses of Shanchol or placebo at an interval of two weeks. Overall, the seroconversion (> 4 fold rise in serum vibriocidal antibodies) against V. cholerae O1 Inaba was observed in 75.5% adults and 72.8% children, while against V. cholerae O139 was observed in 57.5% (60 adults and 78.13% children), 74.53% (64 adults and 76.72% children) and 46.22% (28 adults and 59.98% children) vaccine recipients respectively as compared to 5.7% (7 adults and 4.5% in children), 6.76% (5 adults and 7.5% in children) and 7.28% (6 adults and 8.13% in children) in the placebo groups respectively. No significant differences were observed in safety events between the vaccine and placebo recipients.

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As with all vaccines, appropriate medical treatment should always be readily available in case of a suspected adverse event following the administration of the vaccine. For this reason, it is recommended that the vaccine remain under medical supervision for at least 15 minutes after vaccination.

SPECIAL POPULATIONS

HI-VIIDS

The safety and immune response of Shanchol has not been clinically evaluated in individuals with HI-VIIDS. However, Shanchol is a killed vaccine administered orally and acts locally in the intestine. Therefore, theoretically, the vaccine is not expected to increase the risk of cholera in individuals with HI-VIIDS but the vaccine may not elicit the expected immune response and protection due to underlying immune-suppressive status.

Supervision for at least 30 minutes after vaccination.

Fertility

There are no postmarketing studies of the fertility effects in humans and no evidence that the vaccine is capable of producing harmful effects during pregnancy. The vaccine is therefore not recommended for use in pregnancy or during lactation.

Pregnancy and Lactation

There is no specific clinical data about the safety of Shanchol in pregnancy or lactation. However, based on the general experience with other killed whole cell vaccines, the vaccine is considered safe for use in women of childbearing age who are not pregnant. However, Shanchol is not recommended for use in pregnant or lactating women.

Asthma

It has not been formally demonstrated that the efficacy of Shanchol is reduced in asthmatic patients. No specific clinical data have been collected to support or refute this supposition. However, based on the general experience with other killed whole cell vaccines, the vaccine is considered safe for use in asthmatic patients who are not pregnant.

There is no specific clinical data about the safety of Shanchol in pregnancy or lactation. However, based on the general experience with other killed whole cell vaccines, the vaccine is considered safe for use in women of childbearing age who are not pregnant. However, Shanchol is not recommended for use in pregnant or lactating women.

Fertility

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