Resource May 18, 2016

The oral cholera vaccine Shanchol™ when stored at elevated temperatures maintains the safety and immunogenicity profile in Bangladeshi participants.

Article published in Vaccine on 18-March-2016 by Saha A et al. **[1]**

ABSTRACT
BACKGROUND: The oral cholera vaccine (OCV), Shanchol™ has shown protective efficacy lasting up to 5 years, however, requirement for a cold chain limits its use in resource poor settings. The study was conducted to determine the safety and immunogenicity of Shanchol in adult participants in Bangladesh when stored at elevated temperatures.

METHODS: The study was conducted in Mirpur, Dhaka. Four groups of healthy adult participants received two doses of Shanchol™, kept under standard storage temperature (Group A; 2-8°C) or at elevated temperatures (Group B, 25°C; Group C, 37°C; Group D, 42°C) for 14 days, respectively. Vaccine specific antibody responses were determined.

FINDINGS: 145 participants were assigned to each group. Adverse events were mild not differing among groups. Vaccine stored at elevated temperatures remained stable with cumulative LPS content within admissible limits. Vibriocidal antibody responses were observed in all groups after each dose of vaccine at day 7 and 21 compared to pre-immune levels (P<0.001). Four-fold increases to Vibrio cholerae O1 Ogawa were observed at day 7 and/or day 21 after vaccination in the standard temperature and the three elevated temperature groups, with responder rates of; 76% (95% CI LB; 70%), 80% (95% CI LB; 74%), 69% (95% CI LB; 63%), and 74% (95% CI LB; 68%) in Groups A-D, respectively (P=0.240). Responses were also seen in all groups to V. cholerae O1 Inaba and V. cholerae O139 and in LPS specific IgA response to V. cholerae O1 antigens.

INTERPRETATION: This is the first report to show that the OCV is stable at elevated temperatures, and the safety and immunogenicity profiles are not altered. This information will help formulate global policies for use of the vaccine at higher temperatures, resulting in easier distribution and vaccination costs and decrease logistical challenges to vaccine delivery.

Topic(s): Clinical Studies on OCV [2]
Country: Bangladesh [3]
Outside Link: http://www.ncbi.nlm.nih.gov/pubmed/26896684 [1]

OCV [4]

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