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Single dose oral cholera vaccine development in Cuba: Progresses and challenges

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Statement of the Problem: Despite the existence of effective treatments, cholera continues to be a health problem in third world countries. Thus, cholera vaccination is now recommended by the WHO. Three WHO prequalified oral cholera vaccines (Dukoral, Shanchol and Euvichol) exist; but international need is more than supply. These OCV require a ≥two dose regimens to be efficacious reducing the yield of vaccine doses in a campaign. Thus, a single dose OCV is still pursued. Recently, the FDA registered Vaxchora for the US travel market; however, different dose strength is required and has to be tested in endemic settings. This work aims to study the development of single dose OCV candidate CV638 in Cuba.

Methodology & Theoretical Orientation: The single dose OCV candidate CV638 is under development in Cuba. It has satisfactorily passed phase 0, phase I and II in adults. Thus, a randomized, placebo controlled, phase I clinical trial was conducted in adolescent and children to evaluate the safety and reactogenicity of CV638.

Findings: No serious adverse events or out-of-range clinical laboratory findings were reported in the vaccine or placebo group. The percentage of volunteers with some adverse event (AE) did not reach significant differences between groups. Most AEs detected were mild, although two individuals had moderate fever, one in each group, and one volunteer in the vaccine group had moderate-vomiting related to PI administration. In the CV638 group, the most frequent adverse event was gurgling (25.64%) while in the placebo group were fever (21.46%). Of 39 volunteers receiving CV638, 31 excreted the active ingredient strain in feces, whereas placebo recipients did not. The 15 (100%) adolescents, 13 (86.67%) children aged 9-11 year old, and 8 (88.89%) children aged 5-8 year, seroconverted within 14 days of ingesting CV638.

Conclusion & Significance: We conclude that CV638 was safe, poorly reactogenic and immunogenic in healthy children and adolescents of both sexes. Thus, clinical evaluation may proceed to the next phase.

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